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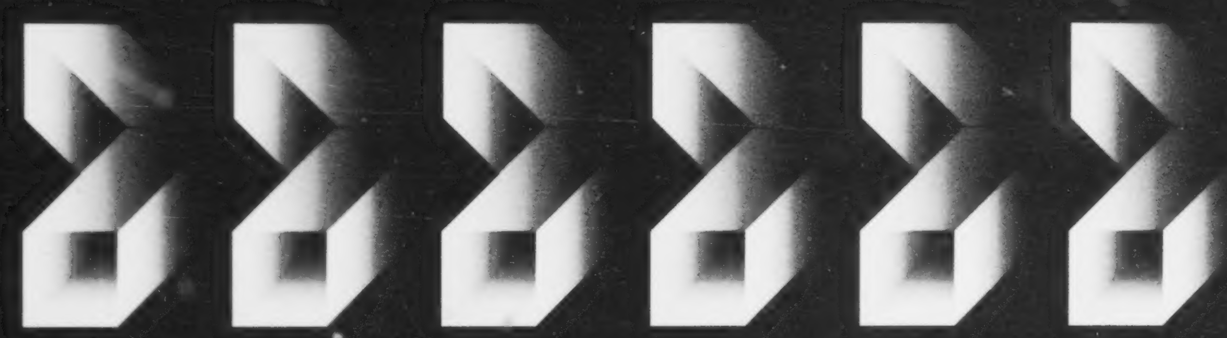

CEPA CASE STUDY: TECHNICAL REPORT #3

EVALUATION OF THE ENVIRONMENTAL HAZARDS PROGRAM

August 1995

Canada

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ASSESSMENTS AND THE PRIORITY SUBSTANCE LIST UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT

by

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The analysis, conclusions and recommendations found in this consultants' report are those of its authors and are not necessarily shared by the Department of National Health and Welfare.

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1. INTRODUCTION

The purpose of this study is to address several questions, on behalf of the Program Evaluation Division of Health Canada, about the performance of the Environmental Health Directorate (EHD) in toxicity assessments of substances on the Priority Substances List (PSL) established under the Canadian Environmental Protection Act (CEPA).[1] These questions, which are presented in Appendix I, fall into two groups. Questions in the first group pertain to the scope and quality of the assessments and the use to which they are put. Questions in the second group are more broadly focussed, and deal with how effectively the EHD communicates with other government bodies and with the general public on matters related to CEPA, and the extent to which the assessments conform to the Health Protection Branch's risk-assessment/risk-management model; their purpose is to consider what lessons might be learned from the first five years of assessing Priority Substances.

1.1. THE PSL ASSESSMENT PROCESS IN HEALTH CANADA

The Bureau of Chemical Hazards tackles its various responsibilities (of which the assessment of Priority Substances is one) using a matrix project system in which resources from more than one Division can be applied to individual projects. This ensures that expertise or knowledge in one Division can be readily made available to a project being led from another Division.[2] The Environmental Substances Division has prime responsibility for CEPA-related projects and the Environmental Contaminants Project (*Project Area 33* [Foster, Dormer and Long (1994)]) is mainly concerned with CEPA toxicity assessments. The objectives of this Project are:

- to identify the hazards associated with environmental contaminants,
- to estimate the risks to human health associated with environmental contaminants,
- to participate in the management of risks to human health associated with environmental contaminants, and
- to communicate the risks to human health associated with exposure to environmental contaminants.

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[1] The toxicity assessments were conducted almost exclusively within the Directorate's Bureau of Chemical Hazards.

[2] The matrix project system is described in the preamble to the *Project Area Reviews 1994-95* [Bureau of Chemical Hazards (1994)].

The first three objectives are equivalent to the Health Protection Branch's risk-assessment/risk-management model (described in, for example, *Risk Assessment/Risk Management: A Handbook for Use within the Bureau of Chemical Hazards* [HPB (1991a)]), which is one of the topics we have been asked to address. The fourth objective, communication, forms a thread through several of the questions that are addressed in this report.

In any attempt to learn from the experience gained in carrying out the first set of assessments under CEPA (namely, the PSL I assessments) there is an aspect of the assessment process that should not be ignored. This is the sheer amount of work needed to carry them out. The task presented by the publication of the first Priority Substances List was a daunting one. It essentially required that the toxicity of 44 substances be assessed within a five-year period — an average of nine a year. Having ourselves had the experience of producing similar assessments, we are fully cognizant of the amount of effort that is required, and the stress that such a workload would entail. And we can only express our admiration that the task was completed, to a high standard, within the allotted time — an accomplishment that reflects the greatest credit on all who were involved.

1.2. APPROACH ADOPTED

In conducting this case study, we obtained information from two main sources — structured interviews with federal-government employees associated with the program[3] and a review of pertinent documentation. Our review of documents for this case study was limited to material supplied by the Environmental Health Directorate and the Program Evaluation Division at the beginning of the study (this material included the assessment documents and supporting documentation for eight Priority Substances selected in discussions with the Program Evaluation Division at the start of the project), and documents identified or provided as a result of the interviews. We did not undertake an independent literature search. The documents that formed part of this review are listed in Appendix II

After familiarizing ourselves with the general aspects of the assessment program through a preliminary perusal of the supplied documentation, a series of interviews was conducted. The initial step involved a short meeting with the contact person identified by the Program Evaluation Division for this case study.[4] During this meeting we briefly outlined the purpose of the case study and asked for names of individuals who would be able to help in answering the evaluation questions (presented in Appendix I). Eight people, within Health Canada (including the contact person) and three within Environment Canada were identified, and face-to-face interviews were carried out.

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[3] It was not part of our mandate to contact individuals outside the federal government.

Two team members were used in each face-to-face interview and, prior to each interview, interviewees were sent outlines of the topics we wished to discuss. After each interview, a point-form account of the session was prepared and sent to the interviewee for comment. Comments (if any) from the interviewees were incorporated in the interview accounts and these accounts then formed one of the bases from which we answered the project's evaluation questions.

The topics discussed during the interviews fell into a number of categories — general background, assessment reports, control-option process, and the Priority Substance process in general — and these are summarised in Table 1-1. The responses to the interviews are summarised in Appendix III.

1.3 OUTLINE OF THE REPORT

In the next chapter of this report we outline the background to the PSL assessment process — the origin of the Priority Substances List, the joint management of the assessment process with Environment Canada, and some decisions that were taken as to the course of the assessments. We also describe how we selected a sample of eight completed assessments for review in this evaluation. We end the chapter with a brief discussion of the role of science in the PSL assessment process.

In Chapter 3, we discuss some aspects of the assessments themselves, beginning with the meaning of "toxicity" under CEPA and how it is interpreted by EHD. From this basis we then assess the quality and scope of the assessments using our sample of eight substances as examples and discuss how they accord with the Health Protection Branch's

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[4] Dr. V.C. Armstrong, Chief, Environmental Substances Division, Bureau of Chemical Hazards, Environmental Health Directorate

TABLE 1-1 *Topics Discussed During the Interviews**

GENERAL BACKGROUND

- INTERVIEWEES' RÔLES IN THE PROGRAM
- THE MANAGEMENT PROCESS IN PSL ASSESSMENT
- INTERACTION BETWEEN HEALTH CANADA AND ENVIRONMENT CANADA
- THE RÔLE OF SCIENCE IN ASSESSMENTS

PSL I ASSESSMENT REPORTS

- EXPOSURE AND CEPA TOXICITY
- RISK ASSESSMENT AND CEPA ASSESSMENTS
- PUBLIC COMMUNICATION
- INDICATORS TO LINK ASSESSMENTS TO HEALTH IMPROVEMENT

STRATEGIC (or CONTROL)-OPTION PROCESS

- BACKGROUND ASPECTS
- CEPA ASSESSMENT REPORTS AND CONTROL OPTIONS
- HEALTH CANADA'S AND ENVIRONMENT CANADA'S APPROACHES TO CONTROL OPTIONS

PRIORITY SUBSTANCE PROCESS IN GENERAL

- THE MEMORANDUM OF UNDERSTANDING
- THINGS THAT WORKED AND THINGS THAT DID NOT
- SUGGESTIONS FOR IMPROVEMENT

* A summary of the responses is presented in Appendix III.

risk-assessment/risk-management model. We then discuss a more general topic related to the assessment process, that of the extent and success of communications with the general public.

The following chapter discusses aspects of the development of control options and deals with the regulatory background to control options, the contribution of the assessment reports to control-option development, and the difficulties in determining the health benefits that could result from the implementation of controls.

In the final chapter we survey our findings, consider what worked and what did not in the assessment process, and make recommendations for approaches to the assessment of new entries on the Priority Substances List.

2. BACKGROUND

This project is concerned with (1) the toxicity assessment of Priority Substances, (2) the process that would lead to measures aimed at reducing exposure to those substances deemed to be toxic (strategic-option development), and (3) the lessons learned from carrying out these activities on substances in the first Priority Substances List (PSL I). In order to provide a context for an examination of these topics, we must first outline the framework in which these activities have taken place.

2.1 HISTORICAL

In any new program activity, the first efforts are inevitably part of a learning process and often lead to procedures being modified in light of experience. Many of the problems, in the case of CEPA assessments, stemmed primarily from the number of assessments that had to be carried out within a comparatively short period, partly from the identity of the substances chosen for assessment, and partly from the organizational structure set up to carry out these assessments. As these features all date from the earliest stages of the CEPA assessment program it is appropriate to briefly review some aspects of the development of the program.

2.1.1 The Act[5] and Its Implications for Priority Substance Assessment

The *Canadian Environmental Protection Act*[6] was promulgated on 28 June 1988 as "an Act respecting the protection of the environment and of human life and health". A requirement of the Act is the compilation and publication (in the *Canada Gazette*) of a Priority Substances List which specifies substances that should be given priority "in assessing whether they are toxic[7] or capable of becoming toxic" [s. 12 of the Act]. The Act goes on to state that if a substance has been on the PSL for five years without being assessed, any person may demand a board of review to conduct the assessment [s. 14] — this stipulation essentially creates a deadline for completing the assessment.

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[5] An excellent review of the evolution and structure of CEPA may be found in the report, *Evaluation of the Canadian Environmental Protection Act (CEPA)* [RFI (1993), sections 2.1 and 2.2], and we will not attempt to duplicate it here.

[6] R.S.C. 1988 (4th Supp.) c. 16.

[7] CEPA has its own definition of the term "toxic", which is different from both a scientific definition and common usage. The definition is presented in Section 2.2 below, and discussed in greater detail in Chapter 3.

An Advisory Panel (commonly known as "the Hall committee" after the name of its chairman) was established early in 1988 and asked to recommend "approximately 50 substances" for possible inclusion in the Priority Substances List [Hall *et al.* (1988)]. This panel presented its report in August 1988 and, from the 50 substances identified in that report, 44 substances (listed later in this chapter in Table 2-1) were placed on the Priority Substances List in February 1989.

To assess 44 substances in five years with any degree of scientific rigour is a major undertaking, especially when it is recognised that for some (perhaps, many) of the substances there were considerable gaps in the information needed to determine CEPA toxicity. Compounding this difficulty were the facts that the organisational structure for carrying out the assessments was new and faced a considerable period of development, the assessment process itself was new, and many of the staff carrying out the assessments were new to this type of work and had to be trained.

2.1.2 Organisation and Management

A key feature of CEPA is that it is the joint responsibility of Health Canada and Environment Canada. Broadly, Environment Canada is responsible for aspects relating to possible harm to the environment, while Health Canada is responsible for aspects of the act that relate to human health (see, for example, Myres [1992]). Environment Canada, however, has sole responsibility for the administration of the Act [Holliday *et al.* (1993), Section 2.1].

With regard to assessments of Priority Substances, joint responsibility is a major advantage. Data on levels of a substance in environmental media, such as air or water, are important in an assessment of both possible environmental damage and human exposure. The same is true for the behaviour of the substance in the environment (i.e., how it gets from its environmental sources to the "targets" of concern). In addition, s. 11(b) of the Act refers to "a danger to the environment on which human life depends", explicitly linking concerns for the environment and human health. As a consequence, both Departments have to be involved in the assessment of each substance on the PSL.

The initial plan was for assessment reports on Priority Substances to be produced using a "task group" approach. A substance was assigned to a task group leader and, working with this leader, individuals from different groups within both Health Canada and Environment Canada would work on the assessment report — the task group leader would be responsible for writing the integrated final report. This activity was carried out under the auspices of the Priority Substances Subcommittee (which had members from Health Canada and Environment Canada) that met regularly until September 1991 (i.e., for first two years of the assessment process), primarily to scope out assessments and to organise Task Groups. Few assessments appear, however, to have been completed under this arrangement.[8]

It was clear from numerous comments received during the interviews that the task-group approach did not work satisfactorily. The main reasons given were (in the words of one our respondents) that:

a) group leaders had little direct control over group members;

b) there was a lack of consistency in the reports produced by different task groups;

c) quality control by management was lacking; and

d) the assessments were (to some individuals' minds) being produced too slowly.

As a result, the task-group approach was abandoned in mid-1991, and each Department produced its own components of the assessments, with Health Canada dealing solely with health matters. All health assessments were reviewed by the same person to ensure consistency. The health and environmental components were then combined by the "lead" Department to produce the final assessment documents.[9]

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[8] Only two assessments, Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans [Environment Canada and Health and Welfare Canada (1993a)], Effluents from Pulp Mills Using Bleaching [Environment Canada and Health and Welfare Canada (1991)], give clear indication of being the joint product of an interdepartmental task group. Two others, Chlorinated Wastewater Effluents and Creosote-impregnated Waste Material [Environment Canada and Health and Welfare Canada (1993b & c)], are identified as being the product of task groups but, in these cases, only Environment Canada participated in the assessments. In all other assessments, there is no reference to task-group activity.

[9] The task-group concept carried with it the "lead" (i.e., it was chaired by someone from the lead Department). Although the task-group concept was abandoned, the lead remained with the Department that would have chaired the task group.

During the period when the task-group approach was still employed, a Memorandum of Understanding was drawn up, defining the relationship between Environment Canada and Health and Welfare Canada in their activities under CEPA [Liston and Higgins (1990)]. This document, dated August 1, 1990, was perhaps intended to resolve problems that were arising from the use of task groups; one of its features was the responsibility placed on both Departments to establish a joint CEPA Management Committee.

This committee is chaired alternately by Health Canada and Environment Canada. Its role, as set out in the Memorandum of Understanding, is to "consider policy direction, program planning, establishing and maintaining work priorities, co-ordination mechanisms, amendments to CEPA and its regulations, the establishment of sub-committees to address specific requirements of CEPA, and any other matters it deems relevant." We are uncertain whether the Priority Substances Committee[10] (which was charged to oversee assessment of Priority Substances) would have been considered a subcommittee, but a Toxic Substances Subcommittee was formed to approve *Gazette* notices and, especially, to give advice on what should be recommended in the way of control options. Recently, a Strategic Options Subcommittee has been set up to investigate ways in which the effects of toxic substances may be mitigated or eliminated.

Early in the assessment process a decision seems to have been made, at least by Health and Welfare Canada, that control options are to be considered subsequent to any determination of toxicity (see Catley-Carlson [1990]). At about the same time, we were informed by one of our respondents, Health and Welfare Canada had decided on its working definition of CEPA toxicity[11] and began a methodical process of working its way through the majority of Priority Substances.

2.2 TOXICITY ASSESSMENTS

In s. 11 of CEPA, the meaning of "toxic" under the Act is defined in the following terms:

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[10] The establishment of which, we think, predated the CEPA Management Committee. The Priority Substances Committee fell into disuse around the end of 1991.

[11] This definition was published in a final form in April, 1994 [Health Canada (1994a)].

> ... a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions
>
> (a) having or that may have an immediate or long-term harmful effect on the environment;
>
> (b) constituting or that may constitute a danger to the environment on which human life depends; or
>
> (c) constituting or that may constitute a danger in Canada to human life or health.

Paragraphs (b) and (c) refer to human interests. Paragraph (b) captures a concern with large-scale environmental problems and possibly deals with concern for future generations (harm to potential humans), while Paragraph (c) obviously is a concern for public health. It is clear to us that Health and Welfare Canada is primarily concerned with Paragraph (c) and is also, to some extent, with Paragraph (b).[12] We assume that s. 11(b) requires joint assessment by Environment Canada and Health and Welfare Canada, while s. 11(a) would be the exclusive responsibility of Environment Canada.

None of the 44 substances on the Priority Substances List was assessed as toxic under section 11(b) of CEPA; under Section 11(c) 18 were assessed as toxic; 13 were nontoxic; for eight there were insufficient data on which to base a conclusion; and for the remainder (5) no assessment was conducted; under Section 11(a) 15 were assessed as toxic; 17 were nontoxic; for 10 there were insufficient data on which to base a conclusion; and for the remainder (2) no assessment was conducted. This is summarised in Table 2-1.

For the purposes of this project, a sample of eight assessments was chosen to provide illustration of the manner in which assessments were carried out and to serve as examples on which to base a discussion of control options.[13] Chemically, the 44 assessments completed can be divided up as follows:

22 chlorinated substances,
12 (unchlorinated) aromatics,
4 metals, and
6 miscellaneous substances.

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[12] Myres [1992] made the same observation.

[13] There were insufficient resources available in this project to review all 44 assessments in depth.

TABLE 2-1 *Results of the Assessment of the PSL I Substances*[14]

SUBSTANCE	LEAD DEPARTMENT	11(A) TOXIC	11(C) TOXIC
aniline	Health Canada	NT	ITC
arsenic	Health Canada	T	T
benzene	**Environment Canada**	**NT**	**T**
benzidine	Health Canada	NT	T
bis (2-chloroethyl) ether	Environment Canada	NT	ITC
bis (2-chloromethyl) ether	**Environment Canada**	**NT**	**T**
bis (2-ethylhexyl) phthalate	**Environment Canada**	**ITC**	**T**
cadmium	Environment Canada	T	T
chlorinated paraffin waxes	Environment Canada	ITC	T
chlorinated wastewater	Environment Canada	T	NAC
chloromethyl methyl ether	**Environment Canada**	**NT**	**T**
chromium	Environment Canada	T	T
creosote waste	Environment Canada	T	NAC
di-n-octyl phthalate	Environment Canada	NT	ITC
dibutyl phthalate	Environment Canada	NT	NT
1,2-dichlorobenzene	Health Canada	ITC	NT
1,4-dichlorobenzene	**Health Canada**	**ITC**	**NT**
3,3'-dichlorobenzidine	Health Canada	NT	T
1,2-dichloroethane	Environment Canada	NT	T
dichloromethane	Environment Canada	T	T
3,5-dimethylaniline	Health Canada	NT	ITC
fluorides	Health Canada	T	NT
hexachlorobenzene	Health Canada	T	T
methyl methacrylate	Environment Canada	NT	NT
methyl tert-butyl ether	**Environment Canada**	**NT**	**NT**
mineral fibres	Health Canada	ITC	T & NT
monochlorobenzene	Health Canada	NT	NT
nickel	**Environment Canada**	**T**	**T & NT**
organotins	**Environment Canada**	**NT**	**ITC**
Polycyclic aromatic hydrocarbons	Environment Canada	T	T
Polychlorinated dibenzodioxins	Environment Canada	T	T
Polychlorinated dibenzofurans	Environment Canada	T	T
pentachlorobenzene	Health Canada	ITC	NT
pulp-mill effluent	Environment Canada	T	NAC
styrene	Health Canada	ITC	NT
tetrachlorobenzenes	Health Canada	ITC	NT
1,1,2,2-tetrachloroethane	Environment Canada	ITC	ITC
tetrachloroethylene	**Health Canada**	**T**	**NT**
toluene	Health Canada	NT	NT
trichlorobenzenes	Health Canada	ITC	NT
1,1,1-trichloroethane	Environment Canada	NAC	NAC
trichloroethylene	Health Canada	T	T
waste crankcase oils	Environment Canada	ITC	NAC
xylenes	Health Canada	NT	NT

T = toxic; NT = not toxic; ITC = insufficient data to conclude; NAC = no assessment.

---

[14] From *Briefing Book (for Officials); Parliamentary Review of the Canadian Environmental Protection Act (CEPA)* [Health Canada (1994c)]. Substances in bold-face type are those chosen for detailed study in this project.

Subject to modification by other criteria, a representative sample of eight might therefore be made up of:

4 chlorinated substances,
2 aromatics,
1 metal and
1 other substance.

And this sample should contain about four substances assessed as toxic under section 11(c), two or three assessed as nontoxic and one or two substances for which no assessment was found possible under that section.

Dividing the chlorinated compounds into aliphatic and aromatic and using the above criteria we selected the chloromethyl ethers (aliphatic, toxic), 1,4-dichlorobenzene (aromatic, nontoxic) and tetrachloroethylene (aliphatic, nontoxic). From the aromatics we selected benzene (toxic) and bis(2-ethylhexyl) phthalate (assessed as toxic, and for which data gaps were identified and further studies recommended); from the metals, nickel, and from the miscellaneous category, organotin compounds, representing those substances for which no assessment was found possible, and methyl tertiary-butyl ether (assessed as nontoxic, but for which more studies were recommended).

2.3 ROLE OF SCIENCE

A recurring theme, both in this case study and in the other studies we are conducting as part of the evaluation of the Environmental Hazards Program, is the need to base decisions and actions on sound scientific principles. (Indeed, it was pointed out by one of our respondents that if Health Canada is to produce assessments that are legally defensible, it must be rigorous in its science.) In the realm of environmental health, this is not an easy ideal to strive for. The scientific uncertainties associated with identifying and quantifying causal linkages between exposure to environmental levels of pollutants and adverse health effects are enormous, and this should not be lost sight of when interpreting the results of assessments and applying them to the development of control options.

Science imposes an analytical rigour which provides a foundation and a framework upon which to base solutions. Properly applied, science makes explicit the gaps in information and requires that, in reaching a given conclusion, one not only identifies the gaps but also explain how they are to be bridged. We caution, however, that the science used must be "honest science". There is nothing to be gained by masking decisions made on the basis of non-scientific considerations by invoking "science" as the rationale, and much to be lost. Foremost, perhaps, is the diminished credibility that an otherwise perfectly reasonable decision would have when (as inevitably it must be) the masking is spotted. If something cannot reasonably be answered by scientific explanation then one should say so and acknowledge that other means have to be used to develop the conclusion.

3. PSL I ASSESSMENT REPORTS

The purpose of this chapter is to review the achievements and limitations of the PSL I assessment process, its effectiveness in public communication and its use of the HPB risk-assessment/risk-management model, as represented by the assessment reports and associated documents. These documents stop short of discussing measures to control risks or to provide indicators of how successful the program might be in controlling risks, topics that fall within the scope of this evaluation. The existing documents are, however, an essential part of the background upon which discussions of such matters must be based; we undertake such discussions ourselves in the next chapter. In this chapter we begin by considering the background to CEPA assessments.

3.1 EXPOSURE AND CEPA TOXICITY

The definition of toxicity given in s. 11(c) of CEPA differs from the traditional meaning of "toxic" in at least two respects, and such a new usage of a common term can be expected to cause confusion. For example, a substance that is not conventionally regarded as toxic to humans (or animals) might be assessed as "CEPA-toxic" because of its effects on "the environment on which human life depends"; 1,1,1-trichloroethane would be a potential example, by virtue of its contribution to the depletion of stratospheric ozone[15] [Environment Canada and Health Canada (1994a)]. Conversely a substance that a toxicologist considers toxic may not be "CEPA-toxic". This second case is the one of interest in a human-health context.

From the standpoint of human health, the crucial difference between CEPA toxicity and conventional toxicity is contained in the phrase "entering or may enter the environment *in a quantity or concentration* ... constituting or that may constitute a danger in Canada to human life or health" [emphasis added]. In other words, a substance is not CEPA-toxic, no matter how "poisonous" it may be, if it is not likely to enter the environment in quantities that may cause harm. Thus, exposure is an essential component of CEPA toxicity — which therefore amounts to a measure of risk — and the fact that this is a legal rather than a common use of the term "toxic" does not make it any less binding. The use of the term "toxic" in CEPA is roughly equivalent to the term "harmful", with the implication that when a substance is assessed as toxic, one may generally expect that control measures will be developed to protect human health or the environment.

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[15] In fact, 1,1,1-trichloroethane was deleted from PSL I because it was included in the Montréal protocol for just this reason.

Such a definition of toxicity under CEPA presents some problems in interpretation for toxicity-assessment purposes. Firstly it implies that a major part of each assessment must be an evaluation of human exposure. The data on human exposure may well be virtually non-existent on the one hand, or on the other, more extensive but less reliable and less consistent than the data available to determine conventional toxicity. In either case, the task of estimating the risk presented by a compound becomes considerably more difficult than simply assessing its "toxicity". But arguably a more difficult problem arises after the risk has been estimated. The wording of the Act includes the phrases "may enter the environment" and "may constitute a danger"; and these uses of the word "may" call for interpretation.

Under the widest interpretation, any conventionally toxic substance "may" enter the environment and cause harm to the general public. But, we have argued elsewhere, this is neither reasonable nor legally tenable as an interpretation. Rather

> ...the courts are likely to interpret s. 11 so as to incorporate a "reasonable probability test". In the circumstances, a court might say that a one in a billion chance of entering the environment in a century is a not a sufficiently high probability so as to say that there is a reasonable probability that the chemical will enter the environment. Similarly, in the case of an extremely low probability of getting cancer, a court would say that there is no reasonable apprehension of danger from this chemical. [Holliday *et al.* (1993), p. 19]

In other words, implicit in the wording of the Act is an acknowledgment of *de minimis* risk, below which it would be unreasonable to declare a substance CEPA-toxic.

To apply the CEPA definition of toxicity, one therefore needs a working definition of *de minimis* risk. For threshold toxicants (essentially noncarcinogens), the situation is simple because there is believed to be a level of exposure (the threshold) below which there is no significant risk to human health. The EHD uses the ratio of the typical exposure to the Tolerable Daily Intake (TDI, an estimate of the threshold) as a basis for assessing CEPA-toxicity: a substance for which this ratio is greater than unity is considered toxic under CEPA [Health Canada (1994)]. This procedure is simple in principle and can be applied consistently for the great majority of cases.

For nonthreshold toxicants (most carcinogens), there is believed to be some risk at any level of exposure. A strict application of the Act would therefore require an *a priori* decision as to what would be a *de minimis* ("acceptable") level of risk. Instead, the EHD has decided that for the purposes of CEPA toxicity assessments there is no *de minimis* risk for carcinogens, and accordingly any human carcinogen is deemed CEPA toxic, whatever its levels in the environment [Health Canada (1994a)]. This decision reduces an assessment of CEPA toxicity to a simple determination of conventional toxicity (and, it is tempting to think, may have been facilitated by the use of the term "toxic" to denote a harmful substance under CEPA).

Risk estimation in the PSL I assessments essentially stops at "risk analysis", the first major component in the HPB risk-assessment/risk-management model (the other component, "option evaluation" is deferred to the subsequent stage of strategic options development, as we discuss in Chapter 4). This too is an approach that is simple and that can be applied consistently.

One consequence of using this approach is that once a substance is identified as a human carcinogen, for the purposes of assessing its CEPA-toxicity, a thoroughgoing exposure assessment is unnecessary. This may result in a major saving of effort, but puts an increased burden on the control options phase: until it is understood how a substance enters the environment and how Canadians are exposed to it, it is difficult, if not impossible, to decide on the most effective ways of controlling it. Other possible consequences of the "nonthreshold toxicants" policy are anomalies in the assessments themselves, and we next discuss such possibilities together with some other aspects of toxicity assessments, using examples from the first Priority Substances List.

3.1.1 The Chloromethyl Ethers

The chloromethyl ethers — bis(chloromethyl) ether and chloromethyl methyl ether — are a prime example of how CEPA-toxicity differs from conventional toxicity, and also of how the EHD working definition of toxicity for nonthreshold toxicants affects the assessment procedure. Toxicological data for these two compounds shows that they are animal and human carcinogens. In conventional terms, then, they would be assessed as toxic, and this is the course the EHD assessment followed. [Environment Canada and Health and Welfare Canada (1993d)] However, for the purposes of CEPA, the probable human exposure to these chemicals should be considered. And then a different picture emerges. Not only are these compounds produced in only very small quantities in Canada (no more than one kilogram per year in 1990 and 1991), but they are destroyed by contact with water with half-lives of less than a second; their persistence in air at room temperature and normal humidity is at most a few minutes [Environment Canada and Health and Welfare Canada (1993e)]. With such properties, the chances of any significant non-occupational exposure to these compounds would be small even if they were major industrial chemicals; at their present levels of use in Canada, the chloromethylethers cannot realistically be said to present any public health risk.[16]

Nevertheless, having committed itself to disregarding the possibility of *de minimis* risks, the EHD was consistent in assessing the chloromethylethers as CEPA-toxic under s. 11(c) of the Act. One can express some curiosity as to why these compounds appeared on the Priority Substances List in the first place. However, given that they were placed on that List, once they were identified as human carcinogens, it seems odd that the EHD carried out an apparently extensive literature search for (rather meagre) exposure data that served only to undermine the basis of the toxicity assessment.

3.1.2 Tetrachloroethylene

A much more complex investigation was carried out in the case of tetrachloroethylene. In this case the position as regards conventional toxicity was probably more complicated and was certainly more comprehensively covered in the literature than was true for the chloromethyl ethers. Tetrachloroethylene is a documented carcinogen in rodents. But the types of cancer induced by it differ between species (liver cancers in mice; kidney cancers in rats); and in the case of rats, the carcinogenic effects are sex-dependent, being limited to males. Such variability raises a doubt as to whether it is justifiable to extrapolate to humans and declare tetrachloroethylene a human carcinogen. The epidemiological data with regard to cancer are comparatively extensive but, at best, inconclusive.[17] Investigations of the mechanisms of toxicity of tetrachloroethylene in rodents indicate that it is its metabolites that are responsible for inducing cancers; the production of these metabolites is sensitive to details of the biochemistry of individual species. In the case of rats, the kidney tumours are associated with the existence of a protein which is specific to male rats. In the case of mice, the relevant metabolite is produced in mice, rats, and humans, but only mice are observed to show significant numbers of liver tumours. It turns out that mice produce this metabolite much more efficiently than do rats (which in turn are much more efficient than humans). The absence of liver tumours in rats exposed to tetrachloroethylene, together with some biochemical evidence suggests that although an animal carcinogen, tetrachloroethylene is not in fact a non-threshold human toxicant, and therefore — even by Health Canada's working-definition of CEPA-toxicity — is not necessarily toxic under CEPA. On the basis of an exposure evaluation, in fact, tetrachloroethylene was found not to be CEPA-toxic under s. 11(c); in this case, the assessment procedure formally accords with the Act as written. [Environment Canada and Health Canada (1993a); National Health and Welfare (1993a)]

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[16] The assessment did not appear to consider the fact that atmospheric lifetimes could be considerably longer in winter when both the temperature and the humidity would be lower than the standard conditions assumed; nor was the toxicity of the formaldehyde produced by the hydrolysis of the chloroethers considered. But it seems very unlikely that either of these facts would change our main conclusion.

The exposure assessment was not very detailed; it did not, for instance try to assess the effects of increases in indoor levels of tetrachloroethylene that arise when dry-cleaned goods are brought into the home (the indoor level may be temporarily as much as fifty times the background level; and fatty foods such as butter exposed to such concentrations can be expected to absorb increased quantities of tetrachloroethylene from the air at such times [Holliday and Park (1991), ch. 3]). It is open to question whether an effort to take into account such effects would have led to a different assessment. And given the facts that tetrachloroethylene was assessed as toxic under s. 11(a), and there is already pressure within the drycleaning industry to reduce consumption and emissions of tetrachloroethylene [Environmental Choice Program (1992)] it seems unlikely that even an assessment of "toxic" under s. 11(c) of CEPA would have a great bearing on the need for or nature of control measures. From this perspective, the effort saved in carrying out a relatively simple exposure assessment may well have been justified.

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[17] All the epidemiological studies dealt with the occupational environment. Effects other than cancer were also the subject of epidemiological investigations and the results were similarly inconclusive.

3.1.3 Benzene

Benzene is unequivocally a human carcinogen (the weight of evidence from case reports and epidemiological studies points directly to its leukaemogenic potential). Recent laboratory studies have also shown benzene to be an animal carcinogen. The main unanswered question concerns its potency. The epidemiological study that is most capable of yielding a quantitative estimate of carcinogenic potency for benzene (an investigation of workers at a rubber-products plant) has only a total of nine deaths from cancer from which to estimate a dose-response relationship; and in it, as in all the studies, there is considerable doubt as to the levels of benzene the workers were exposed to. Nevertheless extrapolation to ambient levels seems to imply significant risk. [Environment Canada and Health and Welfare Canada (1993f)]

Given that the EHD could simply have declared benzene CEPA-toxic as a human carcinogen, it is noteworthy that the exposure assessment is quite detailed, incorporating considerations of environmental transport and fate, and modelling of the distribution of benzene among environmental media [Environment Canada and Health Canada (1993b)] — the kinds of information that are needed for a rational development of control options.

3.1.4 1,4-Dichlorobenzene

Unlike benzene itself, 1,4-dichlorobenzene is not generally carcinogenic in animals. The exception is male rats which show the formation of kidney tumours. As with tetrachloroethylene, this phenomenon is evidently the result of a specific protein in the male rat. For humans the data on health effects are dominated by isolated case reports, for which the levels of exposure are hard to estimate. The predominant symptoms are associated with the nervous system and liver; the limited available data include no evidence for human carcinogenicity. The bulk of other evidence suggested that 1,4-dichlorobenzene is not genotoxic in animals, which would mean that it could be treated as a compound whose toxicity displays a threshold. In these circumstances, the EHD assessment procedure followed the formal definitions of s. 11(c) of CEPA and consisted in comparing a suitable TDI (incorporating uncertainty factors) to the typical exposure of the Canadian public. The daily intake was about two orders of magnitude lower than the TDI, and on the basis of this comparison, 1,4-dichlorobenzene was quite reasonably assessed as not toxic under s. 11(c) of CEPA. [Environment Canada and Health Canada (1993c); Health Canada (1993a)]

3.1.5 Bis(2-Ethylhexyl) Phthalate

Bis(2-ethylhexyl) phthalate (DEHP) is a widely-used additive to PVC polymers, in which it acts as a plasticiser. Its toxicity assessment parallels that of tetrachloroethylene and 1,4-dichlorobenzene, in that there is evidence for carcinogenicity in rodents, but some of the tumours produced are very species- and sex-specific. Furthermore, like these other two compounds, there is evidence that DEHP is not genotoxic in animals. The data on human health effects are once again limited — in particular, there is a lack of information as to the possible carcinogenicity of DEHP. On the basis of the available evidence, DEHP is classified as unlikely to be carcinogenic to humans, and accordingly treated as a threshold toxicant. A no-effects level (expressed as a daily intake per unit body weight) in animals was converted to a human TDI using an uncertainty factor incorporating the effects of different species and the fact of possible reproductive effects.[Environment Canada and Health Canada (1994b); National Health and Welfare (1993b)]

When this TDI was compared with the actual daily intake of DEHP by Canadians, it was about twice the upper limit of the estimates, and would have required DEHP to be assessed as nontoxic under CEPA. However, the exposure estimates are themselves quite uncertain, and exposure through food may have been underestimated owing to the limitations of measurement techniques. The extent of this possible underestimation could be as much as a factor of two, which would bring the exposure level for infants very close to the TDI. Thus, although the best estimates of exposure and the TDI implied that DEHP would be assessed as nontoxic under CEPA, the uncertainty in them (and the uncertainty in the TDI itself could easily be a factor of two) were such that it was considered that it was possible that DEHP could enter the environment in concentrations that might be harmful to some groups within the Canadian public. As a result, DEHP was assessed as toxic under CEPA.

This assessment is formally inconsistent with the EHD's own prescription for the assessment of threshold toxicants; but it is perhaps more usefully viewed as a reminder of the fact that when binary ("yes or no") decisions have to be taken on the basis of continuously variable data — the TDI and exposure estimates in this case — a simple recipe will not always work. There is always the possibility that the data will fall in the range where a simple formula cannot produce a clear-cut "yes" or "no", and judgement must be exercised.

3.1.6 Nonpesticidal Organotin Compounds

For nonpesticidal organotin compounds, there is a general lack of data. In particular there is no basis on which to estimate typical human exposure, apparently not even by physico-chemical modelling. Without such data, an assessment of CEPA toxicity cannot be carried out, unless there are grounds for believing that these compounds are *intrinsically* "nontoxic". Here the assessment seems to have fallen foul of deadline pressure. The supporting document states that studies of mammalian toxicity "have been extracted from reviews and databases" but "have not been critically reviewed by staff at the Department of National Health and Welfare" [Health Canada (1994b), p. 8]. No TDI was estimated.

The only other possible loophole is given by the EHD's prescription for nonthreshold toxicants; that is, if organotin compounds could be shown to be carcinogens, EHD's elimination of *de minimis* risks would automatically allow these compounds to be assessed as CEPA-toxic. Unfortunately, there is only equivocal evidence as to genotoxicity; and among the organotin compounds considered most likely to present a concern for human health, only one cancer study of one compound was found, and while the result of this study was negative, its small scale, coupled with the loss of some of the tissue samples, meant that the results were inconclusive, and no assessment under s. 11(c) was made. [Environment Canada and Health Canada (1993d); Health Canada (1994b)]

We wish that some effort had been made to obtain order-of-magnitude estimates or upper or lower bounds for the TDIs for these compounds and their possible human exposures — if only to confirm that the uncertainties are so great that an assessment was impracticable.[18] Given the lack of exposure data, and the uncertainty as to the genotoxicity of these compounds, however, it does not seem likely that the EHD could have made any defensible assessment.

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[18] In this connection, a reviewer of the draft version of this report stated that "this approach was obviated [*sic*] by a lack of resources (though we are now examining in more detail the data on toxicity for organotins and determining levels in drinking water)".

3.1.7 Methyl *tertiary*-Butyl Ether

Methyl *tertiary* butyl ether (MTBE), a gasoline additive, has limited evidence as to its toxicity. Specifically, there is insufficient evidence to show whether or not it is carcinogenic. In such circumstances, the EHD procedure for assessment of CEPA toxicity essentially treats the compound as a threshold toxicant (noncarcinogen) — estimating a TDI and comparing it to typical human exposure — but with an additional uncertainty factor incorporated in the estimate of the TDI to take into account the lack of data on carcinogenicity. There was insufficient data to make an exposure estimate directly, and human exposure was estimated by numerical modelling, using the physicochemical properties of MTBE and two "worst-case" estimates of releases into the environment based on quantities imported into Ontario or total quantities manufactured in Canada. This procedure is less reliable than using real monitoring data, but the estimated exposure was so much smaller than the TDI (by approximately 45,000 times) that the uncertainties in the modelling were insignificant. Modelling provided a way of circumventing the lack of exposure data and produced good evidence that MTBE is non-toxic as defined under s. 11(c) of CEPA [Environment Canada and Health and Welfare Canada (1992); Environment Canada and Health and Welfare Canada (1993g)]. This use of modelling to circumvent data gaps is relatively new, and illustrates that assessments do not have to be restricted by a lack of monitoring data, provided sufficient physicochemical data are available, together with some basis for estimating releases into the environment.[19]

3.1.8 Nickel and Nickel Compounds

Nickel, like other metals, presents an interesting conundrum. It is an element, and therefore cannot be destroyed; it is present in the Earth's crust and most terrestrial media. What exactly is to be understood, then, by the phrase "entering the environment" as used in s. 11 of CEPA, for a substance which is arguably always present in the environment?

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[19] Since the completion of the draft version of this report, a reviewer informed us that, on the basis of additional work carried out within the Program, designation of a substance as "non toxic" solely on the basis of exposure modelling would no longer be advocated.

The answer to this question, as we have argued extensively elsewhere [Holliday *et al.* (1993), Chapter 3], depends not only on interpretations of "entering the environment" (built environment versus non-built; natural versus un-natural; bioavailable versus non-bioavailable) but also on interpretations of "harm to human life (or the environment)". There is no evidence in the assessment document or the supporting documentation that such questions were ever considered as part of this assessment. Instead, the assessment proceeded along the lines of a traditional toxicity analysis [Environment Canada and Health Canada (undated)] — which glosses over such questions as whether or not the nickel to which most Canadians are exposed is "entering the environment" as the result of human activities or is naturally present.

This matter aside, nickel presents another problem of assessing possible human carcinogenicity based on limited data.[20] The crucial evidence consists of epidemiological studies of metal-refinery workers. All the available studies have limitations, particularly the fact that exposure to other substances than nickel compounds (including, apparently, tobacco smoke) was not explicitly accounted for; the result is a number of pieces of evidence, each unsatisfactory in itself, all pointing in similar directions. Estimates of the carcinogenic potency of nickel compounds (measured as nickel) vary by a factor of 20 among the different studies, but the most reliable one leads to estimates of potency that imply a significant risk to the general population from airborne nickel compounds [Health Canada (1993b)]. On the basis of this weight of evidence there is justification for classifying airborne nickel as a toxic under CEPA under the EHD's procedure for assessing (probably) genotoxic substances. This assessment circumvents (or postpones) the need to investigate questions about the different chemical forms of nickel present in the air, their origins and the extent (and mechanisms) of their toxicity — probably not a major deficiency, given the sparseness of data on the individual nickel species in ambient air.

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[20] The assessment also considered non-carcinogenic effects. On the basis of these, metallic nickel was considered "non toxic" and one type of nickel compound, "soluble nickel", was considered possibly "toxic".

3.1.9 The Assessments in General

The assessments we have reviewed have all been of single compounds or groups of related compounds. Even for these, the data are often sparse and inconclusive. It seems clear that attempts to assess ill-defined mixtures, such as crankcase oil or chlorinated wastewater effluents, face virtually insuperable difficulties if the assessments are to be scientifically defensible. (One can envisage using the "genotoxic-carcinogen shortcut" to declare a mixture toxic under s. 11(c) if such a substance could be identified in it, but this seems to place an intolerable burden on the options evaluation phase. Should options be aimed at controlling only the "trigger" carcinogen? If they succeed in this effort, would it follow that the mixture was really nontoxic?)

In general, the assessments *are* scientifically defensible; the major hazards have been identified, and estimates of their degree have been made using informed scientific judgement. The criteria for assessing nonthreshold toxicants fall outside the letter of the Act. But probably the major point to be made about the assessments in general is that the relationships between human exposure and sources of the pollutants were not fully explored, and as a result the task of devising control options is made more difficult. Given the time and resource constraints under which the assessments were carried out, such limitations are perfectly understandable and, we would argue, quite justifiable.

One of the questions we were asked to address as part of this project was:

> Q2. Are there things EHD should do to help improve the availability of, EHD access to, or quality of information on the toxicity and on actual or potential exposure to environmental hazards assessed under the Canadian Environment Protection Act?

In light of the discussions presented in this chapter, it is clear that there was little problem obtaining information from the published literature, as evidenced by the extensive bibliographies in the assessment documentation. The quality of this information is, however, another matter. In this respect, those conducting assessments have to rely mainly on work done outside Health Canada (i.e., the "quality" is beyond the control of the Environmental Health Directorate).[21] With some exceptions (a couple of which we have noted in this chapter), the information on "traditional" toxicity was quite good. Exposure data, however, were often incomplete, both in terms of the environmental levels of pollutants and their origins. Some of this incompleteness may be due to the limited amount of effort devoted to investigating source/exposure level relationships, but the majority almost certainly reflects the difficulty of determining quantities of pollutants released into the environment and the behaviour, transport, and fate of the pollutants after they are released. In this context, we cannot resist throwing in the truism that given unlimited time, resources, and money anything is possible. And this raises the question as to the amount of effort society is prepared to devote to tackling such problems.

3.2 RISK ASSESSMENT AND CEPA ASSESSMENTS

Part of our mandate in this project is to consider what use was made in the PSL I assessment process of the HPB's risk-assessment/risk-management model. This is one of a number of such models; the various approaches to the use of risk assessment were summarised by one of our respondents as follows:

> There are three general models for decision-making purposes:
>
> 1) the "Harvard MBA approach", with its requirement to develop numerical endpoints on which to base decisions,
>
> 2) the use of "expert judgment", and
>
> 3) the multi-stakeholder approach.

Virtually all jurisdictions that have models for environmental risk assessment (e.g., the OECD countries) develop numerical endpoints to handle threshold toxicants. For non-threshold toxicants, for which a numerical approach would require a low-dose risk extrapolation, the United States is virtually the only country to employ option (1) in environmental-health decision making; the second approach is commonly employed in

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[21] As one of the individuals interviewed observed:

> "The PSL assessment process is long and cumbersome, but there are no obvious ways of improving it except that it would be helpful to identify data gaps sooner in the process — to go from identifying a research need to producing useful data could take from six to 18 months, depending on the nature of the test(s)."

Europe; and, of all of the OECD countries, Canada's approach is closest to that of the United States.

Canada's risk-assessment model as described in the document, *Health Risk Determination: The Challenge of Health Protection*, formally consists of four stages: hazard identification, risk estimation, the development of possible options to manage the risk, and the analysis of those options, in preparation for the subsequent, risk management, phase [Health Canada (1993c)]. Although there are formal, even numerical, procedures that can be applied at almost every stage of the risk-assessment/risk-management process, the model as described in *Health Risk Determination: The Challenge of Health Protection*, "is not intended as a rigid structure in which each of the steps is taken in sequence. Rather, the model provides a general framework within which flexibility can be introduced on a case-by-case basis." [Krewski *et al.* (1993)] This flexibility is necessary, not only to accommodate the complexities and limitations of data that are almost certain to arise when one deals with public health, but also to acknowledge scientific uncertainty.

One might expect, in fact, that deviations from the canonical form of this model would be common among the CEPA assessment documents, in view of the various difficulties presented by limited and uncertain data. These documents, in general, show that considerable effort is devoted to identifying the hazards associated with a particular substance, and some estimate of the risks is made (usually in the form of a limited exposure assessment, but for carcinogens, when there are sufficient data, explicitly as an estimate of lifetime risk). For carcinogens and mutagens, a rough measure of relative risk is provided by the "Exposure/Potency Index" (EPI), which is given by the typical daily intake of such a substance divided by the intake that would be needed to produce a five-percent increase in the incidence of cancer (or other effects of exposure) [Health Canada (1994a)]. The Index provides a basis for assigning priorities among such substances: the higher the EPI, the greater is the actual exposure in terms of the carcinogenic "potency", and therefore, by this criterion, the more pressing the need to reduce exposure.

In general, the effort expended on risk estimation is not unreasonably low. As one of our respondents noted,

> A principle of "diminishing returns" operates in the use of risk analysis in risk assessment/risk management — the (often inordinate) amount of effort required to

> develop a rigorously scientific risk analysis on which to base risk management approaches may be out of proportion to the needs of risk management.
>
> Quantitative risk analysis is not particularly useful in CEPA assessment — most important is overall evaluation of data, not just reliance on a unit risk-number.

The latter point is borne out by the assessment of DEHP as discussed in Section 3.1.5 above.

In fact, the main omission from the HPB risk assessment/risk management model in these CEPA assessments is the consideration of control options, which, as we have noted, has been postponed in its entirety to a separate phase of the assessment process, which we discuss in the following chapter.

3.3 PUBLIC COMMUNICATION

There is a general duty on the Government of Canada set out in CEPA to "encourage the participation of the people of Canada in the making of decisions that affect the environment" [s. 2(d)]. This duty can be put under the heading of public communication — investigating the extent and effectiveness of which is a large part of our mandate in this evaluation. The Act itself offers little guidance on the form that public participation should take or how it should be carried out. The statutory requirements for public communication of CEPA-related material are limited: publication of a summary of the toxicity assessment in the *Canada Gazette*, and availability of the assessment document [s. 13(1)]. Health Canada has gone beyond these statutory requirements in a couple of ways. First of all, the assessment documents themselves refer to background documentation and state that this is also available to the public, and thus is implicitly included in the formal requirement of the Act. These formal requirements were fulfilled for almost all the PSL I substances within the five-year time span (see, for example, Government of Canada [1993a,b]; Government of Canada [1994a-f]).[22]

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[22] In some cases, only draft or unedited versions of the supporting documentation were available at the time the summary reports were published in the *Canada Gazette*; in a few cases — e.g., for nickel — the same was true of the assessment documents.

But, beyond these requirements, the EHD has made considerable effort to communicate the aims and achievements of CEPA to the public, via a series of *Issues* papers, briefing documents and press releases — see, for example, Anon [1993, 1994] and HPB [1990, 1991b, 1993]. Perhaps as the result of time constraints, the series of *Issues* papers is incomplete for the substances whose assessment were published most recently. But the set of briefing documents [Myres (1994)], news releases (and spokespersons identified as being able to deal with media questions on each substance [Doneit (1994)]) was comprehensive and is potentially perhaps more useful. An indication that the EHD is committed to efforts at public communication is the existence of a *Health Risk Communication Handbook*, currently under preparation [HPB (1994)].

The actual effectiveness of such measures is, however, open to question. In the words of one of our respondents,

> The production of CEPA reports was a very expensive activity, particularly in the light of the results achieved:
>
> a) there was little media or public interest in either the CEPA toxicity assessments or the news releases (little or no media coverage evident), and
>
> b) while the Minister was copiously briefed, there were virtually no questions asked in the House.

It was suggested that this lack of interest may have resulted from the fact that the issue of tobacco smuggling and the concomitant reduction in tobacco excise taxes was competing for media attention at the time the CEPA assessment reports were published, but it seems likely that if there had been great public interest in the CEPA assessment documents, it would have become apparent. One might wonder whether a more proactive approach on the part of EHD would have been effective in stimulating public interest — but also whether the cost of such an approach would have been justified, given that there are as yet no "practical" consequences from the assessments.

A possible avenue of communication that was explicitly excluded was stakeholder involvement in the CEPA assessment process. This decision was taken at least in part to avoid exacerbating the already extreme time pressure on the assessment process by introducing further steps and delays [Catley-Carlson (1990)]. Given the extreme time pressure under which the assessments were produced, such a decision is quite understandable.

There was a general consensus among our respondents at Health Canada that efforts to communicate with the public are worthwhile, and agreement that, where possible, such activity should be proactive. But where such efforts at communication actually fit in among the directorate's conflicting priorities and limited resources is less clear-cut. One of our respondents summarised the situation as follows:

> As a general principle, communication with the public is a very necessary activity, but there appeared to be a certain "mindset" within HPB (which permeated down to all levels) that was uncomfortable with this. The EHD, however, probably does more communication (mainly of a technical nature) than most in HPB. The priority accorded communication with the public depends very much on the attitude "at the top" — such communication is always the most vulnerable when it comes to an "economic crunch" (in such circumstances HPB falls back on its basic mandate of science and regulatory activity) — things may change, because the current ADM has identified public communication as a "core function".

Such questions about the priorities to be assigned to public communication may in some cases become academic, when the control-options phase of CEPA is under way: for some substances, modifying public behaviour by education may be the most effective control option available; and for many substances, it may be necessary to "sell" the control options that have been decided on.

4. THE STRATEGIC (or CONTROL)-OPTION PROCESS

The aim of the strategic options process is, ultimately, to develop measures (of both a regulatory and non-regulatory nature) through which the adverse effects of substances judged to be toxic will be lessened or, ideally, eliminated.[23] And within this aim, Health Canada's role is to ensure that, where warranted,[24] protection of human health is the primary concern. The end result of this exercise is risk management; the general principles of which, for the Health Protection Branch, are laid out in the documents, *Risk Assessment/Risk Management: A Handbook for Use within the Bureau of Chemical Hazards* [HPB (1991a)] and *Risk Management in the Health Protection Branch* [Health and Welfare Canada (1990)].

The evaluation questions regarding the control-option process we had been asked to address were:

Q4c What consultations did the Environmental Health Directorate conduct to discuss control implementation strategies;

and,

Q4d What regulations, guidelines, or standards did the Environmental Health Directorate recommend following these consultations? Have these been promulgated? If not, why not?

The short answer to both these questions is: "very little, to date".[25] We shall therefore devote our efforts in this Chapter to exploring the development of the strategic-option process and, using a selection from the eight Priority Substances chosen for consideration in this project, highlight some of the difficulties associated with choosing such control options.

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[23] We would argue that the ultimate goal of controls would be to render the substance "not toxic". Such an outcome is, in fact, considered in CEPA with the s. 33(3) provision, which allows Cabinet to remove a substance from the List of Toxic Substances, if (on the advice of the Ministers of Environment and Health) it is satisfied that the substance's inclusion on the List is no longer necessary.

[24] There will, of course, be instances where human health is not the primary consideration and these would arise for substances (tetrachloroethylene, for example) that have been deemed to be toxic under s. 11(a) of CEPA but have been determined to be not toxic under s. 11(c).

[25] Four substances from PSL 1 (out of the 25 deemed to be toxic) have been regulated (pulp-mill effluents [*Pulp and Paper Mill Defoamer and Wood Chip Regulations*, SOR/92-267 (7 May 1992)], polychlorinated dibenzo-dioxins and dibenzo-furans [*Pulp and Paper Mill Effluent Chlorinated Dioxins and Furans Regulations*, SOR/92-268 (7 May 1992)] and, (by default) through the Montréal Protocol on ozone-depleting substances, 1,1,1-trichloroethane [Environment Canada and Health Canada (1994a)] — none of these four substances is among the eight substances we are addressing in this report. Two, the chloromethyl ethers, will proceed directly to regulation [Government of Canada

4.1 BACKGROUND ASPECTS

There are two aspects of the control option process worth exploring. The first concerns the relationship between a substance's toxicity and control under CEPA, and basically deals with what the Act stipulates in the way of control measures for toxic substances. The second concerns the relationship between control for environmental protection purposes and control from a public-health perspective. The difference between the aims of the these two types of control may partly explain the differences in "philosophy" towards CEPA between Health Canada and Environment Canada — philosophical differences were mentioned by a number of those interviewed from Health Canada and were also alluded to by Resource Futures International [RFI (1993), sections 3.1 and 4.1].

4.1.1 Toxicity and Control Options

In s. 13(1)(c), the *Canadian Environmental Protection Act* specifically addresses the question of regulation in connection with the assessment of Priority Substances:

> **13.** (1) Where the Ministers assess whether a substance specified on the Priority Substances List is toxic or is capable of becoming toxic, the Ministers shall
>
> (a) prepare a report of the assessment;
>
> (b) make the report available to the public; and

(1993a)], without going through the strategic option process — basically, because the substances are not commercial products in Canada at present, these regulations will have a similar effect to the New Chemical Regulations under CEPA. The other 19 substances will be going into the strategic-option process.

We were informed that, quite early on in the assessment process, a decision was made to postpone detailed examination of exposure (i.e., one that detailed the relationships between exposures and sources) — an essential component of control option development and, as we have argued in the previous chapter and elsewhere (see, for example, Holliday *et al.* [1993]), of toxicity determination — to the control-option phase. This decision was dictated by the tight time-frame imposed on the PSL I assessments, the comparatively limited resources available, and the fact that for many of the substances information on human exposure was scanty or non-existent.

(c) publish a summary of the report in the *Canada Gazette*, including a statement of whether the Ministers intend to recommend that

  (i) the substance be added under subsection 33(1) to the List of Toxic Substances in Schedule I, and

  (ii) regulations be made under section 34 with respect to the substance.

One could interpret this section as implying that if, as a result of the CEPA assessment process, the Ministers recommend that a substance be added to the List of Toxic Substances then the Ministers must also have an idea of the types of regulations that would be appropriate for that substance's control and inform the public accordingly.[26] This interpretation closely parallels the approach to risk assessment adopted by the Health Protection Branch[27] — namely, that risk assessment involves not only an analysis of the risks but also an evaluation of the options available to control the risks.

A more flexible interpretation, however, was adopted for the PSL I assessments. Every substance judged to be toxic came with a recommendation, in the *Canada Gazette* announcement, that it be added to the List of Toxic Substances. But, in virtually none of the cases was a recommendation made detailing the type of control regulations that would be appropriate.[28] In the majority of cases the notice of intent to add a substance to the List of Toxic Substances was accompanied by the general statement that:

> Stakeholders will be consulted regarding measures that could be taken to reduce exposure to ["the substance"] and to determine if regulations are warranted under the *Canadian Environmental Protection Act.*

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[26] A similar conclusion is also made in the report, *Evaluation of the Canadian Environmental Protection Act (CEPA)* [RFI (1993), p. 39 and p. 46].

[27] The risk determination model used by the Health Protection Branch for addressing health risks to the Canadian population consists of two main stages — namely, risk assessment followed by risk management. The risk assessment stage consists, in turn, of two components — risk analysis (comprising hazard identification and risk estimation) and option evaluation (comprising option development and option analysis). [HPB (1991a), figure 1]

[28] With the exception of Priority Substances already regulated (PCDDs, PCDFs, pulp-mill effluents, 1,1,1-trichloroethane) only the chloromethyl ethers carried an unequivocal statement regarding the type of regulation contemplated — "The Ministers intend to propose regulations under the *Canadian Environmental Protection Act* to control manufacture, import and use of these substances in order to prevent their entry into Canadian commerce" [Government of Canada (1993a)].

Effectively, this statement indicates that Environment Canada and Health Canada have decided to consider control options subsequent to, rather than concurrent with, the assessment of a substance's toxicity. This decision, at least from Health Canada's standpoint, was made early in the assessment process (see Catley-Carlson [1990]). And, as we gathered from our interview discussions, the decision to defer option development until after determination of toxicity was made mainly because resources were insufficient to permit parallel work on toxicity and control options.[29] There was, however, acknowledgment that all substances declared toxic are candidates for controls and that controls on at least some of the substances need to be developed quickly, if only to bolster government's credibility.

This is not to say that all substances declared toxic would be the object of control activity. The Act does not, however, provide much in the way of direction on this matter. There is no statutory obligation that a substance having been added to the List of Toxic Substances would then be subject to some form of control.[30] Indeed, there is nothing specifically in the Act that requires a substance to be added to the List of Toxic Substances even though it had been assessed as toxic. Resources Futures International observed that CEPA had been amended in 1991 "to remove any automatic requirement to schedule all substances assessed as toxic" and went on to express puzzlement as to the actual purpose of the List of Toxic Substances [RFI (1993), p. 38]. To some extent, we share this puzzlement and can only assume that, for substances on the List for which regulations were not enacted, the List serves as notice of potential regulatory action.

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[29] It was also pointed out that, to avoid unnecessary work, it was logical to consider control options only after it had been decided that a substance was toxic.

[30] However, when the Act was promulgated in June 1988, a substance was added to the List of Toxic Substances when regulations concerning that substance came into force [s. 33 and s. 34].

> 33. (1) Subject to subsections (2) … the Governor in Council may, if satisfied that a substance is toxic, on the recommendation of the Ministers, make an order adding the substance to the List of Toxic Substances in Schedule I.
>
> (2) An order adding a substance to the List of Toxic Substances … is effective on the coming into force of regulations made under subsection 34(1) …
>
> 34. (1) … where an order has been made to add a substance to the List of Toxic Substances … the Governor in Council may, on the recommendation of the Ministers after the federal-provincial advisory is provided an opportunity to render its advice …, make regulations with respect to the substance …

This regulatory requirement became optional the following year when the two sections were amended and now read (in part):

> 33. (1) … the Governor in Council may, if satisfied that a substance is toxic, on the recommendation of the Ministers, make an order adding the substance to the List of Toxic Substances …
>
> 34. (1) … the Governor in Council may, on the recommendation of the Ministers and after the federal-provincial advisory is given an opportunity to provide its advice …, make regulations with respect to a substance specified on the List of Toxic Substances …

Control options of a non-regulatory nature are also considered under CEPA. In the main, such non-regulatory initiatives are set out in Part I of CEPA and deal with objectives, guidelines, and codes of practice. There is a statutory obligation placed on the Minister of Health (and Welfare) to "formulate objectives, guidelines, and codes of practice with respect to the elements of the environment that may affect the life and health of the people of Canada" [s. 9(1)]. While no specific mention of toxic substances is made in s. 9(1), it could clearly be argued that a substance assessed as toxic under s. 11(c) of the Act could be considered an "element of the environment that may affect the life and health of the people of Canada" and hence a candidate for guideline setting.

4.1.2 Health Canada's and Environment Canada's Approaches to Options

From our interview discussions, it seems to be the view of the CEPA Management Committee that the Act itself is to be the primary vehicle for implementing control options; be the options regulatory (through s. 34 provisions dealing with the List of Toxic Substances or, perhaps, s. 46 and s. 47 dealing with fuels) or non-regulatory (for example, through the guideline-setting provisions in Part I of the Act). It is also clear, both from the wording of the Memorandum of Understanding [Liston and Higgins (1990)][31] and from interview discussions, that Environment Canada is considered the

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[31] The relevant sections of which state:

Responsibilities of the Department of National Health and Welfare

...

> (2) In exercising its authority under CEPA Health and Welfare Canada agrees to act in concert and to recommend in a timely manner to the Department of the Environment appropriate action to preserve and improve public health.

...

Responsibilities of the Department of the Environment

...

> (2) Environment Canada agrees to review and propose amendments to the Canadian Environmental Protection Act and its regulations in collaboration with the Department of National Health and

"delivery system" for control options (be they in the form of regulations, guidelines, or what have you). In other words, there seems to be a reluctance to use avenues, other than those provided for by CEPA, to control substances that have been assessed as toxic under the Act. Some of those interviewed (from both Health Canada and Environment Canada), however, acknowledged that the use of regulatory provisions of other statutes was also a possibility.

Environment Canada seems to have adopted a sectoral approach as its first line of attack in developing control options (see, for example, Environment Canada [1992]) — in other words controls would be framed for a particular industrial sector rather than for a given substance.[32] From comments received during the interviews, it appears that Health Canada is somewhat uncomfortable with this approach on the grounds that it may not always be the method of choice for protecting human health. As we have suggested elsewhere [Holliday *et al.* (1993), p. 6], it is unlikely that, for example, a "smelter regulation" or a "textile industries regulation" would really be that effective in protecting the largest number of Canadians, when the impact of such regulations would essentially be limited to populations in the vicinity of such establishments.

A number of individuals from Health Canada expressed disquiet over Environment Canada's insistence on quantitative risk assessment in the development of control options.[33] This disquiet stems from the view that the order-of-magnitude uncertainties associated with such assessments make quantitative estimation of the benefits associated with a particular control option impossible (as is detailed later in this chapter, this is a concern we share). Because of Health Canada's insistence on using science in its CEPA

Welfare in order to address any deficiencies which interfere with or reduce the efficiency and effectiveness with which toxic substances are assessed, regulated and controlled.

(3) In exercising its authority to administer CEPA, Environment Canada agrees to give full and timely consideration to recommendations of the Department of National Health and Welfare.

[32] As was pointed out by one of the reviewers of the draft version of this report, this is not exclusively the case. For some substances (benzidine, for example) a substance-specific approach has been used.

[33] This insistence probably stems from the Treasury Board requirement that a regulatory impact analysis statement (RIAS) be presented with every proposed regulation. Such statements require that the costs and benefits of the particular regulation be identified. Without a quantitative risk assessment, the benefits of a particular regulation cannot be determined in anything but the most general terms — the costs, in contrast, can be determined relatively precisely.

activities, there is a certain reluctance within the Department to be seen to be "playing a numbers game"[34] when it comes to the development of control options.

4.2 CEPA ASSESSMENT REPORTS AND CONTROL OPTIONS

Of the eight substances chosen for consideration in this project, four were assessed as being toxic under s. 11(c) of CEPA.[35] Of these four, the chloromethyl ethers are already slated for regulation [Government of Canada (1993a)] and hence will not be part of the control-option process. The other three — benzene, nickel, bis (2-ethylhexyl) phthalate — are part of the process.

Early on in the assessment process, a decision (in the form of a memorandum from the Deputy Minister of Health and Welfare Canada to the Minister) was made to separate the process of toxicity assessment from the development of control options on the grounds that "the scientific assessment of risk ('toxicity') must be clearly delineated from the development of regulatory measures and should be done by government scientists" [Catley-Carlson (1990)]. This clearly places risk assessment among the problems amenable to scientific analysis. Equally clear, though not explicitly stated in this memorandum, is a tacit assumption that "development of regulatory measures" would involve decisions that go beyond science. For our present purposes, we intend to confine our attentions to the scientific aspects of the control option process.[36]

As we have argued elsewhere [Holliday *et al.* (1993), Chapter 3], put simplistically, the path to toxicity determination leads from the sources of the substance in question, through its behaviour in the environment, human exposure and toxicology, to the final decision on CEPA toxicity, while the choice of control options essentially can be

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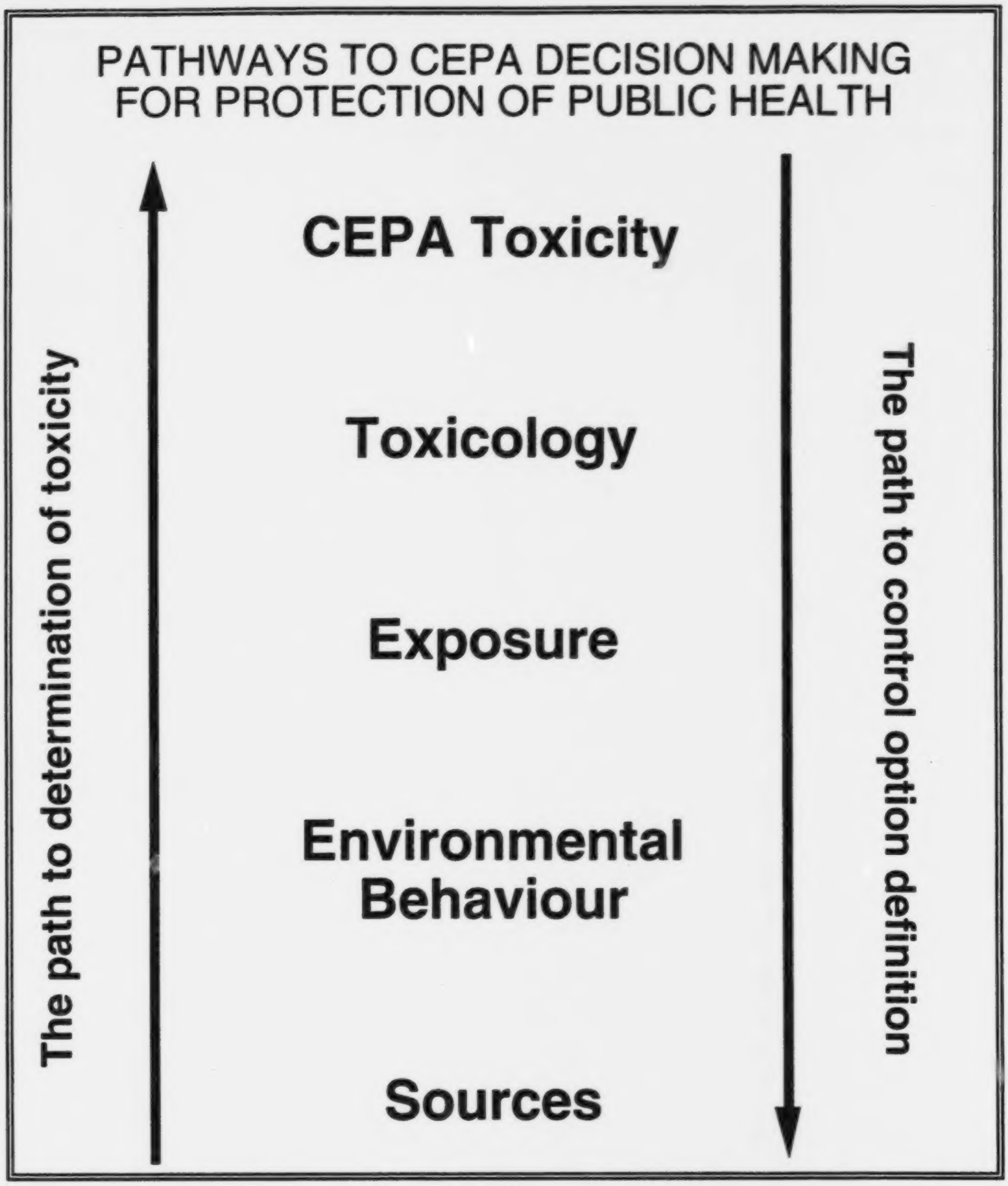
[34] This reluctance is clearly expressed by Health Canada's refusal to present *de minimis* risk numbers in the case of non-threshold toxic substances, relying instead on Exposure/Potency Indices [Health Canada (1994a), section 3.2.1].

[35] These four substances are: benzene, the chloromethyl ethers, bis(2-ethylhexyl) phthalate, and nickel and its compounds. Nickel was judged to be non-toxic in its elemental (metallic) form.

[36] A extended discussion of the interplay between the scientific and non-scientific components in the control-option process may be found in Chapter 4 of the report, *Environmental Health Assessments and Regulatory Options Under the Canadian Environmental Protection Act* [Holliday *et al.* (1993)].

FIGURE 4-1 *Pathways to Toxicity Determination and Control Options Under CEPA* [37]


PATHWAYS TO CEPA DECISION MAKING FOR PROTECTION OF PUBLIC HEALTH
The path to determination of toxicity
CEPA Toxicity
Toxicology
Exposure
Environmental Behaviour
Sources
The path to control option definition

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[37] Figure 3-1 in Holliday *et al.* [1993].

FIGURE 4-1 (continued)

RELEVANCE TO THE CONTROL-OPTION PROCESS

CEPA Toxicity:	"Regulators" need to be cognizant of the bases on which the substance was declared "toxic" because preparation should be made to counter any "challenge" that might arise because of an "unpopular" (but, if the regulators had done their jobs thoroughly, eminently justifiable) control measure.
Toxicological properties:	A knowledge of toxic effects pertaining to the compound is important to the regulator insofar as the type of "illness" that may be associated with environmental over exposure to the compound may determine the type of regulatory controls "society" (the public, interest groups, industry facing regulation, etc.) is prepared to demand or put up with. Of more direct importance is the toxicokinetic behaviour of the compound — it gives the regulator an idea of both the efficiency of uptake of the substance via the different exposure routes and the biological half life and this, in turn, will enable better application of a multi-media approach to the selection of environmental controls.
Human exposure:	The assessment of exposure forms an integral part of the CEPA toxicity determination. Human exposure assessments (which should have been carried out with fullest possible understanding of the substance's toxicokinetic behaviour, if the contributions from different exposure routes are to be properly compared) indicate to a regulator the areas where control options are likely to be most effective.
Environmental properties:	The environmental behaviour of the substance — its transport and fate in the environment — enables the regulator to link human exposure to its sources. In addition, environmental sinks (both identified and suspected, animate and inanimate) can indicate to the regulator where extra attention might be paid, and the environmental half life can suggest the degree to which regulatory controls are necessary and the urgency with which they should be implemented.
Environmental sources:	In any regulatory decision-making process, it is necessary to have the environmental sources identified and, as far as possible, quantified — this information is needed, in conjunction with exposure assessment, to help in the prioritization of the areas needing control measures.

imagined as following the same path in reverse (see Figure 4-1). The key to both these paths, from a health perspective, is human exposure. Human exposure assessments indicate to a regulator the areas where control options are likely to be most effective. We shall explore the implications of this statement using substances chosen from among the eight Priority Substances selected for review in this project.

The assessment for benzene exposure in the toxicity assessment documents [Environment Canada and Health and Welfare Canada (1993f), Environment Canada and Health Canada (1993b)] was comprehensive and showed that, for the average adult, non-smoking Canadian, the largest single contribution to exposure came from benzene in ambient air. The assessment documents also indicated that over 70 percent of this airborne exposure came from transportation activities (principally those involving gasoline-powered vehicles). Such a breakdown of exposure sources is the very kind of evidence that is needed for the development of control options aimed at protecting human health. Clearly, regulatory effort would be wasted if it did not address, as a priority, control of these vehicular emissions. In fact, we would go so far as to say that if nothing were done regarding such emissions, one might just as well not bother to institute any environmental control measures for benzene.

The situation with regard to nickel is much less satisfactory from the standpoint of control-option development. The assessment documents which were obtained during this project [Environment Canada and Health Canada (undated), Health Canada (1993b)],[38] indicated that food is by far the largest exposure source and exposure from ambient air is some three to four orders of magnitude less. Nickel, however, was determined to be toxic on the grounds that it was an airborne carcinogen — the possible toxicity of nickel in food was essentially not evaluated.[39] Nickel is a relatively common element, and natural airborne sources include soil dust, sea spray, vegetation, and volcanoes, but the assessment documents make no attempt to estimate the importance of natural sources to human exposure.[40] This lack of information would hamper control-option development, which requires explicit information on the relationship between sources, exposure and toxicity.

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[38] We did not have supporting documentation dealing with environmental sources, behaviour and fates for nickel compounds.

[39] One of the reviewers of the draft version of this report provided the following observation by way of correction and elaboration:

> "Again, the extent to which it was possible to evaluate the toxicity of nickel in food was limited by the extent of the database. Based on available data on non-neoplastic [non-carcinogenic] effects of soluble nickel compounds (those possibly most likely to be present in food), it was indicated [in the assessment document] that the variation between estimated exposure through ingestion and the lowest reported effect level in an adequate toxicological study was less than the magnitude of an uncertainty factor which might be applied (i.e., it would have been 'toxic' on this basis)."

The assessment documents for bis(2-ethylhexyl) phthalate [Environment Canada and Health Canada (1994b); National Health and Welfare (1993b)] present problems for the developers of control options similar to those discussed above for nickel — i.e., there is a lack of information on the relationship between sources, exposure and toxicity. There are, however, differences in detail. Bis(2-ethylhexyl) phthalate does not appear to occur naturally and, therefore, all human exposures are in principle amenable to control. The concentrations of bis(2-ethylhexyl) phthalate in environmental samples (including human exposure media) arise from its extensive use as a plasticiser for vinyl polymers (including PVC). Equally clear is the fact that for most of the Canadian population[41] food constitutes the major source of intake for the compound. There was sparse indication in the assessment documents of the ways by which food becomes contaminated by bis(2-ethylhexyl) phthalate (a probable result of the sparseness of exposure-level data for this compound). Three pathways occur to us: (1) contamination of human food during processing and marketing (the assessment documents, for example, suggested the possibility of the compound migrating from packaging materials to the foodstuff), (2) contamination at an earlier stage of the human food chain (e.g., biomagnification from animal feed stock), and (3) equilibration of bis(2-ethylhexyl) phthalate in air with the whole food chain. The choice of appropriate control options is, of course, very dependent on which of these alternatives predominate.

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[40] It is interesting to note that airborne concentrations of nickel in Halifax were comparable (sea spray, perhaps?) to concentrations reported in the Sudbury area.

[41] Young children with a predilection for teethers and pacifiers laced with high concentrations of bis(2-ethylhexyl) phthalate are possible exceptions.

It is interesting to note that in some instances efforts were made to generate additional and more pertinent data prior to commencing assessments.[42] Irrespective of how much of the detailing of the exposure routes is appropriate in a toxicity assessment document, the gaps in source-exposure relationships evident in some of the assessment documents are probably a result of the pressure of time and resources under which the documents were produced. Furthermore, given the definition of toxicity for non-threshold substances, it is not clear that a more detailed investigation of exposure would have materially affected the toxicity assessments.

4.3 RISK DETERMINATION AND CONTROL OPTIONS

The Health Protection Branch's risk-assessment/risk-management model, in its canonical form, requires that attempts be made to weigh the costs, risks and benefits of control options.[43] In practice, however, although the costs of a particular control option for a given toxic substance would be comparatively easy to calculate, the health benefits would be very difficult, if not impossible, to quantify.[44]

Such quantification relies on quantitative risk assessment and, as we have already alluded to in Section 3.2, relying overmuch on quantitative risk assessment would be imprudent. The dose-response extrapolations to environmental levels (virtually all of which deal with cancer), on which such assessments are based, contain orders-of-magnitude uncertainties. In the absence of additional evidence, such uncertainties restrict the conclusions that can be drawn to broad generalities that have no quantitative value. In the face of such difficulties, those charged with choosing among possible control options need to be fully cognisant of the limits to the science on which the risk assessments are based.

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[42] For example, a food-basket study was conducted to determine levels of bis (2-ethylhexyl) phthalate [National Health and Welfare(1992)] and nation-wide survey of VOCs in 757 homes in Canada [Otson *et al.* (1992)] provided data on indoor atmospheric levels of tetrachloroethylene.

[43] If a regulatory option is chosen, Treasury Board guidelines for RIASs also require estimation of the risks and benefits [Health and Welfare Canada (1990), p. 50].

[44] For the purposes of our discussion, we are limiting our remarks to the eight Priority Substances selected for review in this project. The toxicity assessments for these substances were essentially based on chronic effects, and we shall confine our remarks to chronic effects. (For acute effects, the quantification of benefits may be somewhat easier.)

The difficulties in risk assessment outlined above lie behind Health Canada's decision not to develop risk numbers (which tend to give a wholly unwarranted impression of precision) in their assessment of nonthreshold toxicants [Health Canada (1994a), pp. 9, 10] — a decision with which we fully concur — preferring instead to develop exposure-potency indices (EPIs). Indeed, as we have also mentioned in Section 3.2, the United States is virtually the only country to employ risk numbers in environmental-health decision making for non-threshold toxicants.

Of the four substances chosen for this project and declared toxic under section 11(c), we shall use the three considered in the previous section — benzene, nickel, bis (2-ethylhexyl) phthalate — to illustrate the difficulties that may arise in trying to apply quantitative risk assessment in the control-option process.

4.3.1 Benzene

The appendix to the report, *Canadian Environmental Protection Act, Priority Substance List Supporting Document Benzene* [Environment Canada and Health Canada (1993b)], provides data from which the EPI value was calculated. These data also imply that the mean concentration of atmospheric benzene in Canada (some 1.3 ppb) could result in four to five deaths from leukaemia per year.[45] Because most of this atmospheric benzene results from the use of gasoline-powered vehicles, a suitably reformulated gasoline might bring about a reduction in human exposure. A reformulation option reducing aromatic content of gasoline from 45 percent to 20 percent would result in a reduction in atmospheric benzene levels of about 25 percent, assuming that all gasoline sold in Canada was reformulated in this way [Park and Holliday (1994), section 6.2] and that there were no transport of airborne benzene from the United States. This would correspond to a "reduction" in deaths from leukaemia of about one death per year — a reduction that would never show up in any analysis of mortality statistics.

It is instructive to speculate on the "cost" of this life saved per year. The volume of gasoline sold annually in Canada is of the order of 3.5 x 10^{10} litres [Environment

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[45] Other analyses of the same epidemiological data on which the EPI value was based suggest that the number of deaths could be considerably smaller (see, for example, an earlier discussion of ours [Holliday *et al.* (1993), Section 3.1.3]). Such observations only serve to highlight the uncertainties attendant on the use of absolute risk numbers.

Canada and Health and Welfare Canada (1993f), p. 4]. If we assume that such reformulated gasoline would cost only an additional one cent per litre, the "cost" of saving this one life would be about $350 million.

Given that benzene has been selected as one of the substances assigned the highest priority for the development of control options (see, for example, the *Briefing Book (for Officials); Parliamentary Review of the Canadian Environmental Protection Act (CEPA)*. [Health Canada (1994c), Section 7]), these figures present the control-option setter with a philosophical challenge. If it were decided that $350 million was too much to pay for a human life (perhaps on the grounds that spending such a sum in a different area might save more lives) it would be necessary to ask what would be an appropriate sum. Once this question is answered, it would then be necessary to choose a control option that could be instituted for that amount — or to decide that controls are, in fact, impracticable.

4.3.2 Nickel and Nickel Compounds

Nickel was assessed as toxic primarily based on carcinogenicity (see Section 3.1.8). Unlike benzene, nickel is naturally present in the environment. It is, as was pointed out in the assessment document [Environment Canada and Health Canada (undated)], the twenty-fourth most abundant element in the Earth's crust. On an elemental basis, virtually all exposure to nickel arises from ingestion. But the evidence for carcinogenicity was limited to inhalation exposure; a route that results, on an elemental basis, in orders of magnitude lower exposure. Presumably, therefore, control options would concentrate on reducing levels of airborne nickel — though, given that the toxic effect is lung cancer, it is difficult to see how the effects of any controls could ever be demonstrated.

There were no data presented in the assessment document as to the relative contributions of anthropogenic and natural sources to airborne levels of nickel. But it was noted that total emissions of nickel from natural sources (soil dust, sea salt, volcanoes, forest fires, and particulate exudate from vegetation) were comparable to those estimated from anthropogenic sources (primary base metal production and fossil fuel combustion). Indeed the document goes on to state that mean exposure levels to airborne nickel in the vicinity of point sources were similar to those in the general population [Environment Canada and Health Canada (undated), p. 60].

This ambiguity presents a problem for control-option decision making. Exposure to natural sources of airborne nickel is not amenable to control under CEPA and, without a knowledge of the proportion of airborne nickel that arises from anthropogenic (and hence potentially controllable) sources it is difficult to judge how effective any control option would be. And, as a result, it would be impossible to estimate the "benefits" of any option chosen. It would therefore be impossible to comply with the requirements of Treasury Board's regulatory impact analysis statements (RIASs).

4.3.3 Bis(2-Ethylhexyl) Phthalate

Bis(2-ethylhexyl) phthalate differs from the previous two examples in that its CEPA toxicity is not based on cancer. It is a substance that has been judged to be a threshold toxicant and, for such substances, the criterion of choice is "a dose (or concentration) … that does not produce any (adverse) effect" [Health Canada (1994a), p. 11]. This dose, with uncertainty factors appropriate to the quality of the data from which it is derived, is used to derive a tolerable daily intake (TDI). The TDI in CEPA toxicity assessments is the *de facto* threshold. The threshold for bis(2-ethylhexyl) phthalate is based on reproductive effects, foetotoxicity, and teratogenicity in mice, and these effects resulted in a uncertainty factor of 1000 being chosen.

The fact that, based on admittedly sparse data, the population exposure to bis(2-ethylhexyl) phthalate is, at worst, close to the TDI implies that measurable toxic effects are unlikely — particularly in view of the fact that those with the largest potential exposures are aged four years or less and therefore not likely to be at risk from a teratogen.[46] This, in turn, makes estimation of the benefits of controls difficult, if not impossible.

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[46] Bis(2-ethylhexyl) phthalate and its metabolites do not accumulate in the body.

4.4 HEALTH -RELATED INDICATORS AND CONTROL OPTIONS

One of the evaluation questions we were asked to address concerns indicators that may be used to judge the effectiveness of the assessments in improving public health.

> Q4(e) What indicators can be developed, or are already available, to illustrate how these assessments might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

Obviously, CEPA assessments by themselves can have no measurable effect on human health. Only when control options are developed and implemented can one hope that CEPA-related activities will begin to bring about improvements in human health.

Ideally it would be desirable to have some way of assessing how effective any control options are in promoting or protecting human health. One of our tasks in this evaluation is to investigate indicators that might be used for this purpose. There is a spectrum of such indicators, ranging from the most explicit (and usually difficult to apply) to the most indirect (and often most easily determined). Which approaches might be considered when control options are available will vary from substance to substance and depend on such matters as the processes by which the substance is transported through the environment and how these influence human exposure.

At the top of the list of possible indicators are epidemiological measures that relate human morbidity or mortality to exposure. Epidemiological studies have been most successfully applied to the occupational environment, but in some cases have been used to investigate environmental exposure. Perhaps the best example is the correlation established between air quality and admissions at hospital emergency departments for cases of respiratory diseases.[Krewski and Burnett (1992)] These cases are, however, of acute illness, and it will be much more difficult to establish similar correlations for chronic illnesses.

One step down from these indicators are measures of exposure, which can be assumed to be related to the degree of health risk. Such measures might be levels of contaminants in food, water or air. These have the advantages of being relatively easy to measure, referring to specific contaminants, and therefore of possibly being related to the effectiveness of a given program. Biomarkers (biochemical changes associated with exposure to environmental substances) provide some direct evidence for human exposure;

unfortunately, they are often harder to obtain than levels in exposure media (requiring, in some cases, blood tests) and have other limitations, as indicated by one of our respondents.

> Biochemical markers are usually too unspecific to be good indicators of (non-occupational) exposure to a given chemical. There are correlations between, for example, levels of environmental contaminants in follicular fluid and fertility rates, but it is hard to show that a given substance is responsible for the effects. But markers may be useful as indicators of exposure to classes of chemical (e.g., evidence of enzyme induction as indicator of exposure to PAHs).

Biomarkers may, in other words, serve as indicators of trends in human exposure to environmental pollutants in general, but they are less likely to provide evidence as to the effectiveness of a specific control measure.

Furthest down the list are the general measures of wellbeing, such as subjective impressions of individuals, which can be assessed fairly easily (by questionnaire, for instance), but are virtually impossible to relate to either the exposure to specific chemicals or the effectiveness of a given control option.

From this spectrum, the middle range of levels in exposure media seems to be the most useful. But levels of environmental contaminants in Canada are low, with the result that the associated incidences of environmental illness are also low, and it would therefore be very difficult to obtain enough reliable data from which to draw conclusions about the effects of individual contaminant levels on human health.

5. CONCLUSIONS AND RECOMMENDATIONS

In carrying out this project, we were forcibly impressed by one fact. The effort needed to carry out the toxicity assessment of 44 priority substances within a nominal period of five years — and in practice probably not much more than half that time — with the resources available to Health Canada is extreme. There was general agreement among personnel we interviewed that the human costs of meeting this deadline were great, and we have every reason to believe it. By any standards we — and our respondents — feel that the quality of the assessments is high. Given the intense time pressure under which they were produced, their quality is outstanding, and we believe the individuals responsible for producing them deserve the strongest commendation for their efforts.

Nevertheless, the pressures involved seem to have left marks on the assessment process — both in terms of the strategic decisions that were made during the process and of the (partial) consequences that arose from the implementation of those decisions. And these facts form a common thread in many of the conclusions and recommendations presented below.

5.1 WHAT IS MEANT BY "TOXIC"?

A number of our respondents mentioned that a word other than "toxic" would be preferred to describe substances that had been judged to be "toxic" under CEPA.[47] This recommendation arose from a realisation that CEPA toxicity differed from the common-usage and scientific definitions of the word — both of which consider a substance's inherent properties as the sole criteria — and that the redefinition by CEPA caused confusion.

None of our respondents suggested that the actual definition of the term "toxic" (or any future alternative) in CEPA should be changed. As we have argued elsewhere [Holliday *et al.* (1993), section 3.1], those who drafted the Act clearly intended to incorporate the concept of exposure into the definition. A term that included this concept would therefore be preferable.

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[47] Resource Futures International, in their assessment of Environment Canada's contribution to the CEPA program, made a similar recommendation [RFI (1993), p. 154].

> *We accordingly recommend that attempts be made to find an alternative term to "toxic" that conveys more accurately the intent of the s. 11 definitions.*[48]

We have no clear-cut alternative. The suggestion offered by Resource Futures International that "toxic" be changed to "poses or is likely to pose a risk to the environment or health" does not strike us as promising. To replace a single adjective, (which is explicitly defined in s. 11 of CEPA) by what amounts to another definition, does not further the interests of clarity. A more promising avenue, to our minds, would be to consider such similar adjectives as "deleterious" or "injurious". Words such as these, convey the concept of degree (of exposure) as well as a substance's intrinsic properties.[49]

In view of the previous paragraphs it strikes us as ironic that the definition employed by Health Canada [1994a] in dealing with non-threshold toxicants under CEPA essentially corresponds to the "traditional" definition of toxicity. This choice, as we pointed out in Section 3.1, obviates the need for a detailed exposure assessment[50] and, furthermore, seems to contravene the spirit of the Act. It seems unreasonable to expect that the Act intended PSL substances not present in the Canadian environment (such as the chloromethyl ethers) to be declared toxic.

> *We would therefore suggest that Health Canada, in its assessment of PSL substances, reconsider its working definition of "toxic" — as defined in the document,* Canadian Environmental Protection Act: Human Health Risk Assessment for Priority Substances [Health Canada (1994a)] — *to bring it closer to that which seems intended by the Act.*

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[48] An alternative to this recommendation would be to make a concerted effort to educate Canadians — or at least stakeholders — as to the true meaning of CEPA toxicity.

[49] The term that we were able to find that seemed closest in meaning to the CEPA definition was "injurious" as in the following example: "Every one of the individuals was affected … injuriously by the alcohol" [Anon (1882)].

[50] We cannot help but wonder if this choice was forced on Health Canada by the considerable time and resource pressure under which the PSL I assessments were conducted.

We feel, however, that any such modified working definition should not rely too heavily on single "risk numbers" (such as may be produced by an unquestioning application of low-dose extrapolation techniques) to conclude whether or not a substance is CEPA toxic. The inherent uncertainties in such numbers are customarily so large that basing decisions on a single value would give a completely unwarranted impression of precision. It was this realisation that led Health Canada to shun the use of risk numbers for non-threshold toxicants but rather to develop an Exposure Potency Index (EPI) to aid in setting priorities for such substances.

These priorities refer to the need for devising control measures. For this purpose, a single number related to exposure, such as the EPI, may be useful; it is not helpful, however, in actually devising specific measures. The more extensive exposure assessments for threshold toxicants are more helpful, but in general they too stop short of what is really needed.[51] In evaluating possible control options, a detailed exposure assessment is almost always essential, if controls are to be devised that are both effective in protecting public health and economically and socially practical. And, it seems to us, such an exposure assessment would be most efficiently carried out as part of the toxicity assessment.

> *We therefore recommend that Priority Substance assessments pay close attention to developing estimates of human exposure. Such estimates require detailed studies of the environmental behaviour of the substances in question, including quantitative estimates of the transport from all sources into human exposure media.*

The benefit of such a move is twofold: it brings the assessment process closer to what is intended in the Act and, as just mentioned, it provides a much needed base from which to consider the selection and development of control options.

5.2 CONTROL OF TOXIC SUBSTANCES

The Health Protection Branch's risk-assessment/risk-management model [Health and Welfare Canada (1990), HPB (1991a); Health Canada (1993c)] incorporates option evaluation in the risk assessment process. There is much to be gained in this approach because, once thinking on a substance has begun, it is more efficient to allow it to proceed through to the final development of options rather than stopping at the toxicity determination stage, only to resume the process at some later date.[52]

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[51] Once again, this may have been the result of the considerable time and resource pressure under which the PSL I assessments were conducted.

> *We recommend that, for future Priority Substances, consideration be given to developing control options in parallel with or soon after the process of toxicity assessment.*

As we have pointed out more than once, there is much in common between the data needed to assess toxicity and those required for option development.

For many of the Priority Substances assessed, the relationship between sources of the substances and exposures was investigated only superficially, if at all. Understanding such relationships is essential to development of effective control options.

> *We would like to suggest, therefore, that in future Priority Substance assessments, greater attention be paid to developing relationships between sources of the substances and human exposure.*

Such investigations would be a natural development of the more detailed exposure assessments we recommended in the section above.

While it may be natural for those working on CEPA assessments to think primarily in terms of control options under the provisions of the Act (regulations, guidelines, public education, and so on), this is not the only approach that could have a bearing on public health. Indeed, as we have argued elsewhere [Holliday *et. al.* (1993), Chapter 6], there are a number of other federal statutes which have components dealing with environmental health and into which Health Canada has input. In many cases, options based on statutes other than CEPA may be more effective in protecting public health, than options based on the provisions in CEPA.

> *Accordingly, we recommend that consideration be given, where appropriate, to including statutes other than CEPA as the basis on which to develop control options.*

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[52] Resource Futures International, in their assessment of Environment Canada's contribution to the CEPA program made a similar observation [RFI (1993), p. 155].

After all, s. 34(3) states that a regulation cannot be made under CEPA if the "regulation regulates an aspect of the substance that is regulated by or under any other Act of Parliament".

5.3 FUTURE PRIORITY SUBSTANCES

Some of our respondents were highly critical of the process by which the first set of Priority Substances was chosen. Indeed, we can sympathize with those who, working under the pressure of the five-year deadline, found themselves having to spend time conducting assessments on substances that, for example, were not present in the Canadian environment. The process established for the selection of the next set of Priority Substances [Environment Canada and Health and Welfare Canada (1993h)] seems to be a great improvement (particularly with regard to the establishment of clear screening criteria and the provision of background dossiers) and promises to produce a more coherent list.

> *We therefore endorse the proposed procedure for selecting the next generation of Priority Substances.*

A major factor in the stress experienced in the efforts to assess the first set of Priority Substances was the need to complete all 44 within five years. Fewer substances placed on the list at any one time would lessen the pressure of the five-year assessment deadline. There is nothing in the Act that requires all substances currently on the Priority Substances List to be assessed before any more are added [see s. 12(1)].

> *Accordingly, we strongly recommend that future additions to the PSL be made in groups considerably smaller than the original 44 and, in the interests of maintaining a reasonable completion rate, that additions to the list be made more frequently than once every five years. (In other words, as one of our respondents suggested, a "rolling PSL".)*

Under such an approach, for example, one could envisage substances being added (in groups of five, say) to the Priority Substance List every six months. Thus, at the end of five years, 50 substances would have been added to the List and assessments would have been due on the first five. The remaining substances (in groups of five) would become due at further intervals of six months. The assessment activity would, of course, be an on-going process with new Priority Substances being continually identified at six month intervals. Such an approach acknowledges the lead time required to conduct assessments (to carry out additional research, exposure surveys, and so on)[53] in that an elapsed time of five years is available for the assessment of each substance, while at the same time alleviating the pressure by staggering the completion dates.

Our final recommendation is based on the fact that the assessment of Priority Substances and the development of control options require a multi-faceted approach. The range of expertise crosses departmental boundaries. Although the use of inter-departmental task groups was found to be infeasible under the circumstances of the initial series of assessments,

> *We would like to suggest that a task-group approach to CEPA assessments be reconsidered.*[54]

After all, CEPA is no longer a new statute, much experience has been gained, and the assessment of Priority Substances can now be considered a mature program.

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[53] As indeed were done for a number of the PSL I candidates.

[54] A reviewer of the draft version of this report expressed the following comments on this recommendation:

"There is no question the it [the Task Group approach] could lead to a better understanding and coordination of assessments between Departments. However, … the problem of Task Group leaders not having responsibility for delivery ....[needs to be addressed]. How is it envisaged that Task Groups would be able to meet deadlines?"

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APPENDIX I: SCOPE OF THE CEPA ASSESSMENT STUDY

The purpose of the study is to:

1. Review eight representative CEPA Priority Substances List (PSL) assessment reports and as needed meet with the responsible officials of the Bureau of Chemical Hazards and with Biostatistics and Computer Applications Division, Environmental Health Directorate, in order to provide a written report addressing the following questions:

   Q4. What have been the program's achievements in assessing substances on the Priority Substances List? What have been the consequences of these assessments?

   - (a) How many assessments have been completed?
   - (b) How many hazards were identified? How serious were the hazards? What has or might have been the extent of public exposure to these hazards?
   - (c) What consultations did EHD conduct to discuss control implementation strategies?
   - (d) What regulations, guidelines, or standards did EHD recommend following these consultations? Have these been promulgated? If not, why not?
   - (e) What indicators can be developed, or are already available, to illustrate how these assessments might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

   Q2. Are there things EHD should do to help improve the availability of, EHD access to, or quality of information on the toxicity and on actual or potential exposure to environmental hazards assessed under the Canadian Environment Protection Act?

2. Comment on the lessons to be learned from the Bureau of Chemical Hazards' participation in the PSL assessment process, and the implications for the Bureau's effective and efficient participation in the PSL II assessment process through answering the following questions on "the actions taken and advice given by the Environmental Health Directorate":

   Q7a. EHD provides information and advice to governments, departments, agencies, and others to help them manage the health risks from environmental sources?

   - (a) Do client decision makers get timely and needed information from EHD on health risks from environmental sources?
   - (b) Does EHD provide the information in a useful format?
   - (c) If EHD didn't provide this information and advice, where would these clients turn for information and advice? What would be the consequences if this were to happen?

   Q6. How effectively does the program communicate with specific interest groups and with the public about actual public exposure to radiation and chemical hazards, and known health risks from such exposure?

   Q1. Do these case studies suggest a need for specific changes or improvements to the way Environmental Health Directorate uses the HPB Risk Assessment/Risk Management framework in planning and conducting its operations? Are there factors that must be addressed which fall outside of the HPB framework?

   The study will primarily focus on Q7a, with a secondary focus on Q6 and Q1 as appropriate.

APPENDIX II: BIBLIOGRAPHY PERTINENT TO THE CEPA ASSESSMENT STUDY

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APPENDIX III: SUMMARY OF INTERVIEW TOPICS AND THE RESPONSES[55]

Interviewees: Eight individuals from Health Canada
and three from Environment Canada:

GENERAL BACKGROUND

Interviewees' Rôles in the Program

- varied.

The Management Processes in PSL Assessment

- Health Canada assisted in the development of PSL I, prepared criteria for selecting PSL II candidate substances (proposing selection criteria and a scoring system for chemicals), and carried out the assessment of health risk of Priority Substances.
- Within the limits of resources and abilities available to Health Canada, the Department is working to ensure that any environmental controls developed under CEPA address health concerns [see specific comments under the heading "Control-option Process"].
- The Priority Substances Section in Health Canada was started in December 1989/January 1990, but Task Groups (which included staff from other groups in the Bureau of Chemical Hazards) had been formed before this date to address individual substances — this proved to be quite ineffective because the staff involved in the Task Groups were already fully committed on such other projects as drinking water criteria.
- The initial plan was for assessment reports on Priority Substances to be produced using a "task group" approach. A substance was assigned to a task group leader and, working with this leader, individuals from different groups within both Health Canada and Environment Canada would work on the assessment report — the task group leader would be responsible for writing the integrated final report. This activity was carried out under the auspices of the Priority Substances Committee (which had members from Health Canada and Environment Canada) that met regularly until September 1991 (i.e., for first two years of the assessment process), primarily to scope out assessments and to organise Task Groups.

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[55] By and large, each bullet corresponds to a response from an interviewee and thus there will be instances of repetition.

- Initially, the assessments were tackled using a task-group approach (a substance was assigned to a task group leader and, working with this leader, individuals from different groups within both Health Canada and Environment Canada produced the assessment report). This approach was not successful because:
  a) group leaders had little direct control over group members;
  b) there was lack of consistency in the reports produced by different task groups; and
  c) quality control by management was lacking.
- Most of Health Canada's actions from September 1990 to February 1994 were interpreted by Environment Canada to be a separation of responsibilities and actions. Health Canada expected the two Departments to produce their respective components of the assessment individually and then combine them, rather than having the Departments work in partnership to produce the documents, which was the original Task-group concept.
- The task-group approach was dropped (in mid-1991) in favour of a parallel system — Health Canada developing the health-related parts of the assessment and Environment Canada, the environmental aspects — the two parts being combined to produce the final assessment report.
- The "task-group concept" was abandoned in mid-1991 and a parallel assessment process instituted (Health Canada doing the health component; Environment Canada, the environmental) — Health Canada felt that they were ahead and did not want to be held back (Environment Canada's problem was partly logistical in that operations were carried out at many, dispersed locations; Health Canada's activities were much easier to co-ordinate as essentially all were conducted in the same building).
- In December 1991, Environment Canada conducted a Program workshop to set the stage for Environment Canada draft guidelines and to overhaul of the Environment Canada program management approach.
- Environment Canada's CEPA assessment program was done as well as possible, given the need to work with a broader set of departmental resources (without line control) and the rudimentary state of development of ecological risk assessment methodologies.
- In preparation for the next phase of assessments, Environment Canada has organised a PSL Focus Group (including Environment Canada, Health Canada, Fisheries and Oceans, Industry Canada, Geological Survey of Canada) — only one meeting has been conducted to date due to conflicting priorities/schedules.

Interaction Between Health Canada and Environment Canada

- The CEPA Management Committee is the formal vehicle for inter-departmental interaction. This committee directs a number of subcommittees (e.g., the now disbanded Priority Substances Committee, the Toxic Substances Subcommittee, and the newly-formed Strategic Options Subcommittee).

- The Commercial Chemicals Evaluation Branch works with the Bureau of Chemical Hazards as full partners in the implementation of part II of CEPA — PSL and New Chemicals, regulation of toxic substances, and so on (all aspects but hazardous wastes).

- The relationship [between Health Canada and Environment Canada] is a partnership, almost in the legal sense, and strictly in the formal sense. The arrangement works on a personal level. There have been some difficulties, but co-operation is good.

- Environment Canada has contacts with Health Canada at least once per week (more frequently if needed).

- There used to be regular informal meetings between Health Canada and Environment Canada, but there are fewer meetings now.

- Health Canada see themselves as being driven largely by Environment Canada's agenda, but are making headway in influencing the process (e.g., through the CEPA Management Committee and its subcommittees).

- There were growing pains with PSL I assessment process — Environment Canada initially did not seem to be meeting deadlines (this created "time pressure" on Health Canada towards end of program) and received (unasked for and unwanted) "advice" from Health Canada.

- In the partnership, tasks were subdivided (Environment Canada dealing with 11(a) and 11(b); Health Canada with 11(c)). There were timing problems: Health Canada were ahead on some projects, behind on others. Matching timelines was an inevitable problem, given the physical separation of and different cultures in Health Canada and Environment Canada.

- Environment Canada and Health Canada have different managerial approaches and talk different languages, possibly in part because of a lack of trust between them. Health Canada's management structures are committee-based. [The respondent] sees committees as outmoded and time-consuming; ineffective in decision-making and problem-solving; and unnecessary in a partnership if people can work together.

- Health Canada believed it was more tightly organised than Environment Canada, and continually criticised Environment Canada for not being on time in the assessment process. There was a sense that even when progress was made by Environment Canada, it would not be acknowledged by Health Canada.

- Health Canada also often questioned Environment Canada's scientific conclusions (e.g., the 11(a) toxicity designation for perchloroethylene). But when Environment Canada tried to question Health Canada's evaluation of, for example, diethylhexylphthalate, there "could be no discussion".

- Environment Canada traditionally uses risk-benefit analysis as part of environmental decision-making and this approach causes disquiet among some Health Canada personnel (who are not always consulted on health-related analyses).

- Environment Canada has fewer technically qualified senior managers than Health Canada — Environment Canada attracts mainly "administrators" to these positions — an explanation, perhaps, for the different "philosophies" towards assessment in the two Departments.
  - At Environment Canada, there was little top-down technical direction concerning the content or quality of assessments. Rather staff were expected to develop their own agenda.
  - There was also much more reliance at Environment Canada on outside expertise (such as contractors) — presumably due to a relative lack of experience in preparing assessments.
- Environment Canada have less quality control and consistency in their portions of the assessment reports than Health Canada — this is probably attributable to the many different groups within Environment Canada (e.g., CCB, CCIW, CWS, and Ecosystem Conservation) being the "lead" for various priority substances, and could also have been due to Environment Canada's lack of experience with conducting assessments.
- The greater resources available to Environment Canada (8 or 10:1 c.f. Health Canada)[56] creates difficulties for Health Canada, both in the perception of what is possible and in its execution.
- Owing to the inequitable balance of Managers between Health Canada and Environment Canada, Health Canada program staff are subject to the political whims of Environment Canada management. Since CEPA-responsible Managers at Health Canada have to deal with numerous issues other than CEPA, they are ineffective, on occasion, in influencing Environment Canada Management on CEPA-related issues. (Environment Canada has many more Managers for any one CEPA-related program than Health Canada.).
- Environment Canada did not seem to plan ahead and appeared to leave everything until the "last minute" — this caused problems for Health Canada because, not having the resources that Environment Canada has, Health Canada needs to plan ahead.
- In 1992, Environment Canada set unrealistic time deadlines and then did not meet them while, at the same time, objecting when Health Canada set "realistic" (i.e., longer-term) deadlines for completion of tasks (a expression, perhaps, of differing management style for "motivating" staff to work efficiently?) — this caused considerable frustration for Health Canada.
- Environment Canada resented the stream of written criticism from Health Canada on environmental parts of the CEPA documents and felt that Health Canada was blaming Environment Canada for inadequacy and backing it up with a paper trail — a consultant/client relationship, rather than a partnership. Environment Canada made a

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[56] This is a claim that is also made in the document, *Briefing Book (for Officials); Parliamentary Review of the Canadian Environmental Protection Act (CEPA)* [Health Canada (1994)]. We did not, however, attempt to independently verify it.

conscious decision not to engage in "wars of words" even if it may pose a longer-term liability.

- In June 1992, because of unhappiness with the partnership, Environment Canada requested a meeting (at the Director General level) to discuss it. Health Canada continually expressed concern about how Environment Canada would accomplish goals and this dominated the meeting.

- In December 1992, Environment Canada needed to push certain goals to move its own program and to show ability of the whole program to deliver; sensed that Health Canada felt they had not been consulted.

The Rôle of Science

- The Bureau of Chemical Hazards accepts the consequences of doing science and making all recommendations based on science.

- The CEPA program, almost of "legal" necessity (if eventual decisions have to be defended), must be rigorous in its science.

- If Health Canada does not do the "science", other entities (who may use less rigorous approaches), will.

- Environment Canada would not want to go outside Health Canada for health advice.

- For "toxic" substances, human health is the most common concern in phone calls from the public; the public want independent, science-based advice and conclusions.

- Science-based cultures (such as exist in Health Canada and Environment Canada) are prone to expound problems rather than help find solutions. They tend to want greater and wider certainty, rather than focusing on defining and getting the key information on which to base a decision. (Public distrust of government science perhaps makes scientists more inclined to insist on certainty.)

- Are managers aiding ministers to ask the right questions of their scientists? Is the scientific effort unrelated to the real priorities? (How does one justify to the public, in terms of improvements in health or well-being, the amounts of money spent on government science and technology?)

PSL I ASSESSMENT REPORTS

Exposure and CEPA "Toxicity"

- The assessment of the CEPA s. 11(c) definition of "toxicity" is the sole responsibility of Health Canada — that of s. 11(a), Environment Canada's, while assessment of s. 11(b) could be considered a joint responsibility of Environment Canada and Health Canada (see, for example: Myres [1992]). The definitions came into force with the promulgation of the Act in 1988.

- The "grey" area of CEPA toxicity, s. 11(b), is essentially carried by Environment Canada and deals mainly with ozone depleting substances and global warming. The tacit assumption in these cases is that if a substance is ozone depleting it is "toxic".[57]

- Health Canada's working definition of toxicity under s. 11(c) of CEPA was developed initially in October 1991 and was subsequently refined and published (see, *Canadian Environmental Protection Act: Human Health Risk Assessment for Priority Substances*, [Health Canada (1994b)].

  "Threshold" substances require the development of a Tolerable Daily Intake (TDI); "non-threshold" substances are tacitly assumed to be "toxic", irrespective of extent of exposure.

  The definition caused some problems with some sectors (e.g., the mining industry), which requested that the risk be "non trivial" before a substance is declared "toxic".

- Health Canada had some debate on how to deal with non-threshold toxicants (essentially carcinogens) under s. 11(c). This was finally resolved late in 1991 with the decision that non-threshold substances would automatically be considered s. 11(c) toxic.

- Environment Canada in general doesn't deal with nonthreshold toxicants, but had problems with Health Canada's nonthreshold-toxicant assessment approach, primarily because it had implications for risk management. "Cancer" pushes a button with the public — hence a need to "do something". Furthermore, Environment Canada interprets "toxic" substances as those whose adverse effects government should be committed to remedy. The logic behind a carcinogen being "toxic" when it is not present in Canada is difficult to accept based on definition of "toxic" in CEPA.

- There was concern that some substances, such as chloromethyl methylethers — which are carcinogens but not used or produced in Canada — have been assessed as "toxic" under CEPA (despite lack of known exposures) on the basis of the nonthreshold toxicant policy. After considerable discussion, this decision was accepted as a preventative measure against the introduction of these chemicals into Canada — equivalent to a new substances regulation.

- Animal toxicology is relatively well-defined, but for human epidemiological studies exposure assessments are much less well-defined. Nevertheless, in PSL I assessments there were few, if any, debates over which studies an evaluation should be based on.

- Because of resource and time constraints, detailed examination of linkages between human exposure and pollutant sources was postponed to the control-option development phase.

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[57] Health Canada has decided that there is a health risk associated with depletion of stratospheric ozone and has linked this risk to emissions of ozone depleting chemicals — see, for example, Bouchard [1991].

- Exposure assessment is absolutely necessary, in every case, to the determination of CEPA toxicity and to prioritization of the consideration of options for exposure reduction. Reliable exposure data, however, were difficult to find for many of the PSL I substances (the situation should improve with PSL II because the availability of data will be one of the criteria on which the substances are chosen).

- By and large, for most of the PSL I substances, one exposure route predominated and toxicity assessment must concentrate on this route — the same will likely be true for PSL II substances. (As a pertinent aside: cigarette smoke is a source — often the major source for smokers — of many of the PSL I substances and this makes one question why a Government would make a priority of assessing and examining options to control exposure to environmental pollutants while the sale of tobacco products is still permitted.)

- There is a need to develop better exposure assessment protocols with the aim of using, as far as possible, real monitoring data in exposure assessments, and attempts should be made to "validate" fugacity models. An investigation is being conducted into the viability of using "uncertainty analysis" to characterize population distributions with respect to exposure assessments, rather than relying on mean exposure values.

- One cannot defend the *de minimis* approach for non-threshold substances — presenting a single "number" indicating a particular absolute "risk", expressed as excess numbers of cases per unit of the population, conveys an erroneous impression of precision. It is not science. For this reason, Health Canada developed the Exposure Potency Index — a combination of quantitative estimates of carcinogenic (or mutagenic) potency, within and close to the experimental range, and exposures — as a guide for establishing priorities for further action.

- The Health Canada policy and approach avoid "putting them in a box" — allow flexibility in dealing with nonthreshold toxicants and avoid picking critical risk numbers that may later turn out to be too high; the approach allows efforts to be focused better and produces results sooner than a rigid, number-based approach

- The approach adopted with regard to non-threshold health effects in determining CEPA toxicity has placed Health Canada "in a box" when it comes to the option-evaluation phase of risk assessment — one needs "pretty strong evidence" to get out of the "box".

- Exposure had major influence in determining how the assessment process would be approached and the extent to which the data would be examined, and influenced the final decisions in all eight of the substances in the evaluation sample.

- For methyl *tertiary*-butylether (MTBE), exposure assessment (including modelling) was a critical element of the "nontoxic" assessment.

- For nickel, the route of exposure is critical; the route of exposure and the form of nickel were vital concerns in its assessment as a nonthreshold toxicant. For the metals, natural exposures are unavoidable (though perhaps controllable); the main concern is with anthropogenic contributions to exposure.

- For perchloroethylene, exposure was critical in its evaluation; Health Canada followed a rigorous weight-of-evidence argument, with a critical evaluation of the literature.

Risk Assessment and CEPA Assessments

- Risk assessment (comprising risk analysis and risk evaluation) provides the "structure" leading to risk management; its application must be based on "reasonableness" and the realization that it is no panacea for decision making.

- There are three general models [of risk assessment] for decision-making purposes:

  1) the "Harvard MBA approach", with its requirement to develop numerical endpoints on which to base decisions;
  2) the use of "expert judgment"; and
  3) the multi-stakeholder approach.

  The United States is virtually the only country to employ option (1) in environmental-health decision making; the second approach is commonly employed in Europe; of all of the other OEDC countries, Canada's approach is the closest to that of the United States.

- A "principle of diminishing returns" operates in the use of risk analysis in risk assessment/management — the (often inordinate) amount of effort required to develop a rigorously scientific risk analysis on which to base risk management approaches may be out of proportion to the needs of risk management.

- Quantitative risk analysis is not particularly useful in CEPA assessment — most important is overall evaluation of all data, not just reliance on a unit-risk number. [see Armstrong, V.C. and Newhook, R.C., "Assessing the health risks of Priority Substances under the Canadian Environmental Protection Act", *Regulatory Toxicol. Pharmacol.*, **15**:111-121 (1992)].

- One has to be very aware of the limitations of quantitative risk analysis — unless the data sets on which extrapolations are based are very good (and, in the case of animal data, possess a solid relationship to the equivalent human response), uncertainties may well be in the orders-of-magnitude range. The IARC [for example] does not, in general, provide quantitative risk estimates, arguing that to do so would be scientifically indefensible.

- Toxicology is a means of hazard identification and toxicological risk assessment has to be treated on a compound-by-compound basis.

- The value of negative results (in well conducted studies) is often overlooked in risk assessment work — a pity, in that such studies may prevent others from wasting their time and may provide a useful indication for NOAEL determination

Public Communication

- As a general principle, communication with the public is a very necessary activity, but there appeared to be a certain "mindset" within HPB (which permeated down to all levels) that was uncomfortable with this. The EHD, however, probably does more communication (mainly of a technical nature) than most in HPB. The priority accorded communication with the public depends very much on the attitude "at the top"[58] — such communication is always the most vulnerable when it comes to an "economic crunch" (in such circumstances HPB falls back on its basic mandate of science and regulatory activity) — things may change, because the current ADM has identified public communication as a "core function".

- There are two parts to communicating the results of risk assessment/management activities to the general public — the public's perception of risk [see, for example: Slovic, P., Flynn, J., Mertz, C.K., and Mullican, L., *Health-Risk Perception in Canada: A Research Report to the Department of National Health and Welfare,* 93-EHD-170. Ottawa, Ont.: Supply and Services Canada (1993)] and the ability of the public to understand what is being communicated

- There is a need, therefore, to ensure that HPB's communications are understandable and this is the purpose of the document — *Health Risk Communication Handbook,* FINAL DRAFT: Revision #2. Ottawa, Ont.: Health Protection Branch, Health Canada (March 1994) — currently under preparation.

- There is a need for more proactivity in communicating with the public (if HC has done some thing to be proud of, it should let people know about it) — HPB, perhaps because of its scientific orientation, has an "ivory tower" approach (they wait for the people to ask for information).

- The Bureau of Chemical Hazards would like to be able to anticipate the public's needs for information but, because of limited resources, has generally to act in a "reactive mode" — PSL II process (with stakeholders involved from the start) may bring about an improvement in this state of affairs.

- The Bureau of Chemical Hazards is aware of the need to "educate" journalists and public interest groups (though the latter tend to be highly politicised).

- Communications are complicated by the fact that CEPA is a joint program. There has to be links between Health Canada and Environment Canada at all levels (program, communications, "political" aspects) and it is a major challenge getting consistent messages both "up the line" to the respective Ministers and to the "outside" (other government departments, special interest groups, the general public). Within Health Canada there is also a great deal of co-ordination involved in order to ensure a consistent and unified health message from the various units (co-ordination of CEPA with, e.g.: Foods Directorate, Monitoring and Criteria Division, the various research units within the Branch). External CEPA communication involved:

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[58] The respondent remarked: "Communication, for example, became very much the 'in thing' during Catley-Carlson's era as Deputy Minister."

  a) working through the Canada Communications Group to produce the assessment reports;
  b) preparation of briefing notes, news releases, and question-and-answer documents as background to the assessment reports; and
  c) preparation of "public" material (CEPA pamphlet, HPB *Issues* papers).

- Statutory requirements are the publication of a notice in the *Canada Gazette* and provision of assessment reports. The background documentation that accompanies these assessment reports is aimed at industry; the assessment reports themselves are aimed mainly at the scientific community in general.

- The formal communication requirements under CEPA are: *Canada Gazette* notices, assessment reports, and background documentation.

- The appropriateness of the data supplied in the assessments is not a problem since the requirements were predefined; but there was a tendency for the reports to be too technically written for the average reader, perhaps as a consequence of the efforts made to ensure scientific quality.

- The production of the CEPA reports was a very expensive activity, particularly in light of the results achieved:
  a) there was little media or public interest in either the CEPA toxicity assessments or the news releases (little or no media coverage evident), and
  b) while the Minister was copiously briefed, there were virtually no questions asked in the House.

  Given that numerous surveys have shown that there is considerable public interest in chemicals in the environment, this lack of "success" can only be ascribed to the attention-grabbing issue of tobacco smuggling and the concomitant reduction in tobacco excise taxes that occurred at the time the CEPA assessment reports were published.

- Media backgrounders have been developed for some Priority substances and a limited number of *Issues* papers have been developed (e.g., dioxins and furans, CEPA in general): Backgrounders were intended for distribution to media; Health Canada personnel who have to respond to media questions were provided with additional anticipated questions and answers; *Issues* papers are designed to be given to the general public and the media.

- Health Canada also produced and is developing *Issues* documents related to CEPA substances.

- *Issues* papers are a useful publication tool for the HPB, but are not really marketed. (*Issues* papers are being produced on "toxic" substances and other substances that, while not being deemed "toxic", are of potential concern.)

- Health Canada may be at forefront in communicating findings to public (e.g. *Issues* papers), but the work done for PSL I was a missed opportunity for interdepartmental program communication.

- Because of budgetary constraints, the public-communications aspect of CEPA is not currently being pushed.

Indicators to Link Assessments to Health Improvement (Q4e)

- Assessments, by themselves, don't improve human health — it is only when strategic options are implemented is there a chance to improve human health. Clearly there was insufficient early consideration given by Health Canada management to the organization and work necessary to successfully address strategic options at the end of the toxicity-assessment process in any kind of meaningful time frame.
- Very little attention has been paid to the question of indicators because of lack of time and resources (all effort went into completing the assessments).
- There is a lack of indicator information to show how the Environmental Hazards Program has been effective in protecting and improving the health of Canadians — currently the Program uses a "scientific best judgement" approach; some statistical indicators are available, but not specific enough or rigorous.
- Stakeholders are concerned at the large amounts of money spent for the PSL I assessments, largely in reviewing old science (not developing new science), with as yet little to show in terms of improvements to the environment or human health.
- The political climate is such that indicators of program effectiveness are very necessary — this led to manager-identified indicators such as: numbers of meetings/reports/presentations etc. — but CEPA is not really designed to collect indicators.
- Possible indicators [of program effectiveness] cover a whole spectrum — from the very specific (health outcome statistics), through biomarkers of exposure, proxy indicators (levels in environmental media), general environmental statistics, to WHO indicators of population health (longevity, infant mortality, public perception, etc.).
- Epidemiology in which observed effects can be related to exposure to the toxicant of interest would be the tool of choice — e.g., the work currently underway relating air-quality indices (predominantly ozone levels) to emergency admissions to hospital in southern Ontario for respiratory problems — but for most environmental pollutants this is not possible.
- It is very difficult to use morbidity and mortality statistics as an indicator of program effectiveness in regard to exposure to environmental levels of pollutants (as opposed to occupational levels).
- Biochemical markers are usually too unspecific to be good indicators of (non-occupational) exposure to a given chemical. There are correlations between, for example, levels of environmental contaminants in follicular fluid and fertility rates, but it is hard to show that a given substance is responsible for the effects. But markers may be useful as indicators of exposure to classes of chemical (e.g., evidence of enzyme induction as indicator of exposure to PAHs).

- Exposure levels are a practical surrogate indicator — all that would be then necessary would be to link activities of a given program to a reduction of human exposure (a task, in itself, that would, in most cases, pose considerable difficulty).

- Given monitoring data, one can show whether exposure is decreasing, but a concomitant change in well-being may not be demonstrable. A possible exception is the association between air pollution and admissions to hospital emergency departments (essentially a measure of an acute response) — baseline levels are being determined, so it may be possible to relate a change in human health to the results of health promotion/protection programs. But such an approach is considerably more difficult to apply to chronic effects.

- Levels of pollutants are a key to the indicator question — part of the gathering of appropriate data depends on other groups within Health Canada (e.g., Foods Directorate, Consumer Products Division), and a work team has been established to foster intra-departmental co-operation.

- The main problem is that pollutant levels in Canada are, in general, very low and therefore morbidity/mortality and other health-outcome indicators are difficult to collect (possible opportunity of using eastern European countries' data as "calibration").

- A useful role for the Monitoring and Criteria Division might be the development of health-outcome indicators using monitoring data.

STRATEGIC (or CONTROL)-OPTION PROCESS

Background Aspects

- Purpose of the control-option task is risk management under CEPA.

- CEPA includes an obligation to specify intention to regulate together with "toxicity" in *Gazette* announcements.

- All "toxic" substances are candidates for controls — from a health-protection viewpoint, the priority given them depends, in part, on the "potency" of the substances and the extent of exposure.

- Twenty five substances on PSL I were deemed toxic; four are now regulated; two (the chloroethers) are proposed directly for regulation; the remaining 19 will be going into the control-option-evaluation process: some will be treated on a substance-by-substance basis; some will be treated sectorally (e.g. in Al smelting, both PAHs and fluorides will be examined; in the steel industry, metals, fluorides and PAHs); some substances may end up with both substance-based and sector-based regulations. (For PAHs, the greatest single source is Al production; after that there are a number of comparable sources.) In practice, perchloroethylene controls will be almost sectoral, because of the use pattern (human exposures are also environmental point sources).[59]

- The strategic options process was introduced at the "9th hour". [The respondent] considers that there had been a lack of focus on the whole picture — the emphasis was almost exclusively on getting assessments completed, with little consideration as to what should be done next.
- In 1991, the control-options question was first considered by Health Canada and plans for a Toxic Substances Section were drawn up. But, because of limited resources and the fact that virtually all CEPA efforts were going into completing the assessments, that Section did not come into being until 1993.
- Organization of Toxic Substances Section came in very late — 2 years ago on paper, but really only in the last 6 months.
- The opportunity of developing a process and a structure for control options concurrently with assessments in the early days of CEPA was not taken because of other priorities (e.g., need to complete assessment documents).
- A similar learning process (to that encountered with the PSL I assessments) is now underway with regard to control options — recent reorganization at Environment Canada requires that the inter-departmental relationship be worked out again (this is largely accomplished now).
- In the past, options evaluation was seen as relying almost exclusively on command and control to achieve environmental goals (partly a myth). [The respondent] prefers "anticipation and prevention" to "command and control" (hence "strategic" rather than "control" options).
- The approach now is to look at all available options (regulatory and non-regulatory) and incorporate socioeconomic considerations into the decision-making process. (If banning a substance would close down a town whose population, knowing the risks, was willing to live with the substance, should one impose such a ban?)
- The strategic options group has been talking with, and listening to interested parties (Environment Canada, Health Canada, other Departments, industrial associations, NGOs, ENGOs, the provinces, *et al.*) for five months to help plan the approach to strategic options development.
- Action outside CEPA is being considered [by Health Canada] where appropriate (e.g., Food and Drug Act, Consumer Products Act).
- Strategic Options is a sensitive area with regard to federal/provincial jurisdiction. For Environment Canada the jurisdictional issues are clear; they are less clear for Health Canada.

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[59] We would not entirely agree with this last statement, because in our opinion (see for example Holliday *et al.* [1993]), a major component of population exposure to perchloroethylene is the perchloroethylene absorbed on drycleaned articles being brought into the home environment, rather than emissions from dry-cleaning establishments.

- The strategic-options process inescapably involves negotiations with the provinces, because environment is more a provincial than a federal responsibility; some control measures may be purely provincial.

- NAFTA requires that any control measures not be seen as trade barriers; the development of strategic options will be scrutinised by the US and Mexico.

CEPA Assessment Reports and Control Options

- In the past, when in doubt, Health Canada has taken the most conservative approach with a view to protecting human health, leaving cost-benefit analyses to others. (Even though small changes in pollutant levels may produce no demonstrable improvement in public health, as a general rule any "turning off of the tap" is considered desirable.) The need to develop control options may force changes in this policy.

- There is confusion in the public mind between PSL I, ARET, etc. and there is a need to bring in some control options for PSL I substances pretty quickly to bolster government credibility.

  ARET (accelerated reduction and elimination of toxics), for example, originated with industry and has a goal of developing voluntary controls rather than regulations. It is a phased process. ENGOs. however, wanted immediate elimination of toxics and withdrew from the process, perhaps feeling that to continue to be part of it would cause them to lose credibility. The process requires understanding and compromise.

- Four substances, out of the 15 or so substances declared CEPA-toxic, had been chosen by Health Canada for control-option development over the next two years, the purpose being to assure the Minister of Health that those substances with the greatest immediate concern to the health of Canadians were being given top priority. But subsequent bilateral negotiations between Environment Canada and the provinces (notably on the sector-by-sector approach chosen by Environment Canada) cast doubt on whether all of these four substances will in fact be dealt with first.

- The Toxic Substances Section is not set up to tackle risk assessment (e.g., quantification of risk), but needs this as a tool to develop risk management goals. The assessment reports were not, however, produced with risk-management in mind:

  1) There was a lack of exposure assessments (both with regard to levels in exposure media and how those levels relate to the sources of the substance) which makes it difficult to target appropriate areas for control. Especially missing are linkage of sources of emissions to exposure and interpretation of environmental fate data in exposure assessments.

  2) The use of the Exposure Potency Index with "non-threshold" substances (perhaps an inevitable step towards numerical risk assessment, given Canada's proximity to the US and its approach) probably raises more questions than it answers and does not remove the need to weigh different risks as consequences of control options; furthermore, the use of EPIs makes it hard to argue against the application of

numerical risk assessment or cost-benefit analyses, which Environment Canada favours.

- Population exposure estimates are a necessary component of CEPA option development.
- Health Canada didn't want to make numerical risk assessments, because to do so would require a judgement of "acceptable" risk which by definition needs to address socio-economic considerations.
- With regard to CEPA control-option development, Environment Canada is proposing a formal cost-benefit analysis approach (which would require quantitative health-risk estimates). Because it considers such an approach to be scientifically indefensible, Health Canada is very reluctant to go along with this.
- The risk management process will highlight the flaws in the PSL I assessment process.
- There is a Toxic Substances Subcommittee set up under the CEPA Management Committee and this subcommittee decided on responsible action by government — approving Gazette notices and, especially, giving advice on what Ministers should recommend in the way of control options. Health Canada is an equal partner in this subcommittee, briefing industry on the meaning of assessments and discussing options with stakeholders.
- A Strategic Options Subcommittee has been recently set up under the CEPA Management Committee.[60]
- Lifespan and quality of life are both increasing — are we, therefore, putting too much emphasis on pollution control?

Health Canada's and Environment Canada's Approaches to Options

- The co-relationship (partnership?) between Health Canada and Environment Canada imposed by CEPA should have resulted in a common thrust in the control-option process, but this has not happened.
- Environment Canada views its rôle as regulating for both environmental and health reasons — the "delivery system" for Health Canada.
- Initially Environment Canada appeared to be developing control options without input from Health Canada — this situation has now been rectified, to some extent, by Environment Canada agreeing to have the control-option process approved by CEPA Management Committee.

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[60] One respondent did not understand the real value of this new subcommittee and would prefer to do without it and expand terms of reference of the Toxic Substances Subcommittee.

- The control-option process was initiated by Environment Canada in late 1992 with the arrival of its report, *A Proposed Process for the Preparation of Strategic Options Reports to Reduce Discharges of "Toxic" Priority Substances and Other Substances of Concern*. This report raised some concern within Health Canada:

  > Health Canada was not asked to participate in the production of this report, but was merely asked to comment on it.
  >
  > Health Canada's response to the report was that control-options (like CEPA itself) were a joint responsibility with Environment Canada — the report was, however, released without Health Canada's concerns being either addressed or acknowledged.

- A dichotomy exists between an eco-system approach (and/or sector-by-sector) and a substance-by-substance approach. There are three main options — command and control approach, voluntary compliance, economic instruments (permits/permit-trading) — and the approach to control options is still being formulated.

- Environment Canada favours a sectoral approach to controls in the interests of industry expediency and efficiency — such an approach would be difficult to handle when dealing with health (it would imply that all substances associated with a given industry's emissions be assessed before sectoral control options could be developed).

- The sector-by-sector approach seems to be an essential factor in Environment Canada operations. Health Canada felt this was not compatible with CEPA PSL substances and this difference in viewpoints has not yet been resolved.[61]

- As a result of a 1993 reorganization within Environment Canada (with staffing started 1993-94) development of a control-options process under CEPA became the responsibility of Environment Canada's Response Assessment Directorate — a body with much wider concerns than CEPA controls. ("Transparency" in the strategic options process is a concern of this Directorate — involving, for example, stakeholder and provincial participation, and less direct ministerial responsibility.)

- Since January 1994, Health Canada is being fully consulted in setting up the control-option process, but appears to be treated more as a "consultant" than as a partner.

- A Strategic Options Subcommittee has now been set up under CEPA Management Committee and is chaired by Environment Canada. Health Canada is under-represented on it, with two out of about eight regular participants.

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[61] The respondent added: Environment Canada, for example, is discussing sectoral environmental controls with the provinces, on a bilateral basis, without involving Health Canada. The sectoral approach is now being reconsidered, in part because of concerns raised by provinces — it is a question of jurisdiction; a sectoral approach can be equated with site specificity, e.g. aluminum smelting in Québec.

- Health Canada should be prepared to act on the findings of the assessments within its own Department, under the provisions of Part I of CEPA, by developing guidelines, etc.

PRIORITY SUBSTANCE PROCESS IN GENERAL

Memorandum of Understanding

- Health Canada is clearly identified as advisor on all health matters under CEPA (Health Canada, traditionally, has been health advisor to many Departments).

- The Memorandum of Understanding is a recipe for a broad framework and not really a factor in the daily management of CEPA, as details were worked out through CEPA Management Committee.

- [The respondent] has not personally seen the MoU dealing with Priority Substances, but feels that, in general, MoUs can be useful in delineating rôles and responsibilities. Such documents can be useful at the administrative/management level but may not have much effect at the working (assessment) end of things.

- A renegotiated MoU (if such a renegotiation is considered necessary) to more clearly spell out the statutory obligations of a partnership between Health Canada and Environment Canada under CEPA may cause problems as Health Canada does not possess sufficient resources to be an equal partner.

Things That Worked and Things That Did Not

- CEPA process appears to be working smoothly and efficiently (the "New Chemicals Notification Program" development, for example, was essentially friction free).

- The need to recruit and train staff for a new program with a new approach in a comparatively short time caused difficulties.

- Extreme pressure exerted by the statutory 5-year deadline — senior management (as well as external groups such as the press) almost expected failure.

- Many of the problems in completing the PSL I assessments stem from a lack of holistic planning by managers in the early stages.

- People worked and the 44 assessments were completed; project management and information systems identified difficulties and successes, but the dedication of people was crucial. Support of senior management was critical, especially in the last 6 months of the PSL I assessment process.

- Forty-four assessment reports were completed within the mandated 5-year period but, because of time constraints a decision was made early in the program not to involve stakeholders in the assessment process.

- Despite frictions and occasional lack of trust, both Departments got the job done — but at great human cost.

- All the assessment reports were completed within the 5-year time-frame required by CEPA — but at great personal cost.

- The production of most of the assessment documents occurred in a very short period at the end of the 5-year assessment process, and this caused considerable stress.

- The major career rewards and penalties based on delivery/non-delivery of the PSL I assessment reports on time imply the wrong values for governmental culture.

- All assessments are scientifically well substantiated, rigorous and of high quality.

- In general, the quality of the assessments was very high.

- The CEPA assessment process was a learning curve — there were a number of problems in the early days (e.g., preparation of assessment documents is ideally a joint production, but this proved impractical and it was found more feasible to prepare the health and environmental sections separately and "marry" the two parts at the end) — but CEPA Management Committee (four individuals meeting every six weeks, with more frequent telephone conversations as necessary) and its sub-committees has worked very well in managing CEPA (no decisions have needed a vote, all were consensus decisions).

- Other "affected" Departments were absent initially from CEPA evaluation process and therefore reluctant to provide information. These Departments (e.g., Fisheries and Oceans, Industry Canada) are now getting involved — requests from these Departments for information were made early in the process, but little was provided.

- The "command and control" approach (which is, to some extent, implied in CEPA) is always the preferred proposition — this led to a realisation that control-option development had to be done after the assessment of toxicity (consultations on control-option process have been held with other government departments, and examination of the individual substances and/or sectors will begin shortly with stakeholders).

- The task-group approach initially adopted in CEPA assessment led to inconsistencies in the quality of assessment documents and was in effect dropped — a parallel assessment process was used for most of the documents with Health Canada dealing solely with health matters (all health assessments were reviewed by the same person to ensure consistency) and Environment Canada dealing with environmental matters.

- The choice of PSL I was a haphazard process with no apparent planning — no thought was given as to what substances should be on the list and substances submitted for consideration were poorly researched. As a consequence, the substances chosen caused problems for the assessment process (both from the standpoint of the number of substances that had to be assessed and, for some of them, from an inappropriate choice of substances.).

- Health Canada and Environment Canada had almost no influence over the choice of PSL selection panel and little participation in the final choice of substances — choices were often arbitrary, based on personal preferences of the panel members.

- Health assessments cannot be conducted on some complex mixtures (e.g., waste crankcase oils).

- The dislocation between Health Canada and Environment Canada caused difficulties.

- Dealing with Environment Canada proved very difficult throughout the PSL I assessments (see comments above regarding, planning, deadlines, consistency/quality control). But Health Canada, for its part, was also difficult at the beginning of the assessment process due, in part, to Health Canada's wholly inadequate reallocation of already over-committed resources to attempt to deal with the legislative mandate for Priority Substances. The situation is now improved on both sides.

- The inevitable friction has now been resolved for the assessment process and largely resolved for the Strategic Options Process (this process has a good chance of working to everyone's benefit because all stakeholders are involved).

- Health Canada has less resources than Environment Canada to apply to CEPA.

- The PSL I assessment process has been strongly criticised for its lack of transparency and accountability; this creates a credibility gap in dealing with stakeholders.

- Latter-stage requirement for briefing of industry and of other Departments, "almost sunk" the project. Considerable criticism was received, but this may have exorcised difficulties, as there was no subsequent "flashback" from stakeholders [when the PSL I assessments were published in the *Canada Gazette*].

- Some industries criticised the substance-by-substance approach [in the assessments] and the definition of toxicity. (In addition, federal definitions may not be consistent with provincial or international definitions.)

- The approach to the choice of PSL I was very proscribed (a criticism has been expressed that the panel choosing the substances lacked a certain level of expertise). The PSL II process is shaping up to be a more open and transparent process with a good cross section of "expert" representatives — equal representation from 4 sectors (industry, NGOs, provincial and federal government, science/academia) — but ENGOs virtually boycotting the process as they are feeling very disenfranchised.

- PSL II will be quite different: there is now a trained staff; the procedures and working relationship are worked out — "two trained armies" anxious to start again; but loss of resources must be avoided.

- CEPA Management Committee oversees management of PSL II. Throughout PSL II, full partnership is evident and practised. Health Canada is a full partner in the development of proposals. Both Ministers agree on the panel, process and product.

- Health Canada and Environment Canada have input into criteria for selection of substances for PSL II (suggested criteria include weighting according to such factors as evidence of use in Canada); Health Canada and Environment Canada are involved in screening candidates for the selection panel, and will be among the stakeholders on the panel.

- The new systematic approach to selection of PSL II substances should produce a more intelligent List; and the process of selection will help generate the data needed for the assessment. Health Canada has developed a database on *ca.* 600 substances, and Environment Canada a database on about 50 substances, from which dossiers on PSL II candidate substances will be compiled and made available to the selection committee.

Suggestions for Improvement

- There needs to be a dialogue between Environment Canada and Health Canada for agreement on what form the partnership should take — Environment Canada's guidelines may form a suitable basis for this.

- An improved understanding is needed with Environment Canada on deadlines and management approach to deadlines, and on the degree of quality required for the assessment reports.

- Clear deadlines need to be set.

- An early warning system is needed for the identification of data gaps in the assessment process, with the possibility of "stopping the clock" to enable the required data to be generated (together with a concomitant requirement to co-ordinate research to address the information gaps).

- There is a need for a commitment to doing research and for a policy to avoid or control the "Unable to Assess" problem encountered in some of the PSL I assessments (or at least make it more public).

- With present resources available for CEPA in Health Canada, the number of substances to be assessed under PSL II needs to be reduced (from the 44 assessed under PSL I) — alternatively, more resources would have to be allocated to the task.

- More resources should be made available to Health Canada or, alternatively, fewer substances should be slated for assessment — resources are needed, in particular, for control-option analyses.

- Consideration should be given to the establishment of a "rolling PSL" with smaller numbers of substances (i.e., less than the initial 44) being added to List before assessments of all substances previously on the List have been completed — this is now the proposal, i.e. a PSL every 3 years.

- The PSL assessment is one small step towards a result. It seems premature to announce PSL II before all the lessons from PSL I have been learned, the strategic options process worked out, and the human costs of meeting the PSL I deadline ameliorated.

- Some thought should be given to improving intra-Department communications (with Foods Directorate, Consumer Products Division, etc.) in the development of Strategic Options.

- The current administration is very keen on "transparency" — i.e., ensuring that stakeholders are represented on the PSL II panel and, perhaps, that they be consulted during the assessments.

- With regard to the question of "transparency", some experience/knowledge was gained later in the program. A number of needs were apparent:
  - better public accessibility to process while assessments are in progress (try to keep activity below Ministerial level);
  - inclusion of input from nongovernmental experts; and
  - a non-legislative process (that was considered) to give indications to public of progress in assessments and an opportunity to comment (e.g. announce in *Canada Gazette* when draft is available, and give 60 days for public response).

- The question of "transparency" of the assessment process needs to be explored (stakeholder input vs. "peer review") — while industry input during the assessment might help encourage an early "buy-in" by the interest groups, it would be of little use to the assessment of health effects (identified industry experts would generally be consulted at the technical peer-review stage).

- "Transparency" is not likely to be an impediment in the PSL II assessment process — better choice of substances (due to improved selection criteria and background documentation); defusing of criticism right from the start (draft reports would be provided to industry for comment during the assessments) — ENGOs would not be involved (their choice, perhaps to avoid the appearance of being "co-opted").

- A better process for selection of Priority Substances than that used for PSL I is needed — the current efforts (selection of a representative panel of technically-competent individuals; the drawing up of a list of substances with attendant dossiers from which the selection will be made;[62] government representatives on the selection panel) are promising improvements, but "politics" in the selection of panel members has lately begun to creep in.

- The panel charged with selecting the PSL II almost certainly will not (and should not) consider control-options as criteria for deciding which substances should be considered for PSL II.

- If a sector-by-sector approach to control options is to be implemented, then thought must be given to how this approach will affect the selection of substances for PSL II, bearing in mind that assessment of health effects will, of scientific necessity, still have to be conducted on a substance-by-substance basis (e.g., if one wants to control fuels, the assessments of such substances as benzene and 1,3-butadiene would already have had to be done).

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[62] The respondent added: Screening substances for PSL II was initiated by Health Canada in December 1991 — such a lead time (which was not possible for the choice of PSL I) is necessary for the rational selection of substances for assessment and promises to result in a better choice of substances — Environment Canada did not initiate work in this area until much later (i.e., mid-1993).

- Is there too much emphasis on generating more lists of toxic substances and not enough on doing something about those on the current lists? It may be to industry's advantage to have the government generate and evaluate lists of substances rather than putting the same effort into developing strategic options; such list-generation might delay environmental "control" by a decade.

- Consideration should be given to changing the word "toxic" in the Act to another description — this would minimise the misunderstanding (particularly in the minds of the public) between its common-usage definition and its special Section 11 definition.

- A term other than "toxic" in CEPA would likely have removed most of the communication's problems in applying the working definition of CEPA toxicity.

- Better descriptions of human exposure are needed in the assessment reports, integrating Environment Canada environmental fate assessments with levels found in exposure media.

- Assessments could have greater impact on human health if there was more interaction with other Health Canada groups (e.g., indoor air and food are often more important sources of exposure for humans than outdoor environments).

- The PSL assessment process is long and cumbersome, but there are no obvious ways of improving it except that it would be helpful to identify data gaps sooner in the process — to go from identifying a research need to producing useful data could take from six to 18 months, depending on the nature of the test(s).

- The assessment process provides considerable opportunity for comment and reaction (both in-house and from outside); it is better for the process to take time and be done well than for it to be hurried and open to criticism.

- Amalgamation of evaluation functions within the Bureau of Chemical Hazards would help conserve resources.

- The imbalance between resources available to Environment Canada and those available to Health Canada (at least 5:1) needs to be addressed in the PSL II control-option process.

- The number of substances for PSL II is not yet finalized; it could provide problems for Health Canada if resources are insufficient to properly assess the environmental and health impacts.

- Health Canada and Environment Canada worked jointly on choosing a shortlist for PSL II, with dossiers providing an overview of the available toxicological and epidemiological information; funding is being made available for interveners.

- Is the Green Plan itself outdated now? Will plans for e.g. PSL II be modified by the current parliamentary review of CEPA?